TECHNICAL SPECIFICATION

ISO/TS 21831

First edition
2020-01

Information model of Chinese materia medica processing

Reference number
ISO/TS 21831:2020(E)

ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Fax: +41 22 749 09 47
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

Contents

Page

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 215, *Health informatics*.

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

Chinese materia medica is widely utilized as a part of complementary and alternative medicine throughout East Asia and western countries. In order to ensure the quality and therapeutic effect of Chinese medicines, it is important to use a proper manufacturing process of Chinese materia medica.

There are guidelines for processing Chinese materia medica in the Traditional Chinese Medicine industry, and clinical trials are already available. A large number of relevant trials have been conducted to assess the function of decoction pieces of Chinese materia medica. However, the descriptions of processing in reports tend to be insufficient for the interpretation of heterogeneity among trials, often causing difficulties for data synthesis in meta-analyses. This arises from two reasons: firstly, because of the lack of use of an appropriate information model of the processing of Chinese materia medica, and secondly because semantic associations between concepts of Chinese materia medica processing have yet to be explicitly identified.

In order to address these problems, this document defines the information model within the field of Chinese materia medica processing.

Information model of Chinese materia medica processing

1 Scope

This document specifies an information model within the field of Chinese materia medica processing. It defines a set of domain constraints of sanctioned characteristics, each composed of a relationship and an applicable information model.

This model aims at representing the concepts applicable to Chinese materia medica processing in the making of decoction pieces.

This document is not applicable to Japanese traditional Kampo medicine.

2 Normative references

There are no normative references in this document.

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 General

3.1.1
concept
internal conception of some thing; general notion or idea of some thing

[SOURCE: ISO/TS 18876-2:2003, 3.1.3]

3.1.2
entity
any concrete or abstract thing of interest

3.1.3
relationship
association between two or more *entities* (3.1.2) indicating the purpose or type of association

Note 1 to entry: Can also be known as an association when the information model is based upon object classes.

3.1.4
information model
graphical and textual representation of *entities* (3.1.2) and the *relationships* (3.1.3) between them

Note 1 to entry: Can also be known as a data model, a conceptual data model, a logical data model, an entity relationship model, an object class diagram, or a database definition.

[SOURCE: ISO/IEC 19763-12:2015, 4.2.24]

3.2 Characterizing categories

3.2.1
traditional Chinese medicine
TCM
traditional medicine that originated in China, and is characterized by holism and treatment based on pattern identification/syndrome differentiation

[SOURCE: ISO/TS 17948:2014, 2.2]

3.2.2
Chinese materia medica
CMM
medicinal parts of medicinal plants, animals, and minerals after preliminary *processing* (3.2.4), which are used as raw materials in Chinese medicines

Note 1 to entry: This refers to the raw materials used to make decoction pieces.

[SOURCE: ISO 18668-1:2016, 3.2]

Note 2 to entry: Preliminary processing can include washing and drying. Large and bulking items can also be cut into smaller pieces or shorter lengths.

3.2.3
decoction piece
prescription medicine processed from *Chinese materia medica* (3.2.2) under the direction of *traditional Chinese medicine* (3.2.1) and *processing* (3.2.4) methods for Chinese medicines, which can be directly used in clinical practice or the production of prepared medicines

3.2.4
processing
physical or chemical technique of converting *Chinese materia medica* (3.2.2) into *decoction pieces* (3.2.3) based on the theory of pharmacology of *traditional Chinese medicine* (3.2.1), the *nature of Chinese materia medica* (3.2.30), the need for dispensing, *preparation* (3.2.19) and clinical application

Note 1 to entry: This definition is taken from Reference [24].

3.2.5
toxicity
ability of a substance to produce an adverse effect upon a living organism

[SOURCE: ISO 472:2013, 2.767]

3.2.6
effectiveness
accuracy and completeness with which users achieve specified goals

[SOURCE: ISO/TS 20282-2:2013, 4.7]

3.2.7
adjuvant material
substance added during *processing* (3.2.4) in order to enhance the therapeutic usefulness of pharmaceutical herbal medicament treatment

Note 1 to entry: Adjuvant material is different from excipient material. The latter is usually used to produce pills or tablets, inseparable from tablets, etc. But the solid adjuvant material is discarded after processing.

[SOURCE: ISO/TS 18062:2016, 3.4, modified — Note to entry has been modified.]

3.2.8
channel tropism
meridian tropism
orientation of the medicinal action according to the meridian/channel on which the therapeutic action is manifested

Note 1 to entry: This definition is taken from Reference [20].

3.2.9
moisture content
amount of water contained in *decoction pieces* (3.2.3) after *processing* (3.2.4)

Note 1 to entry: General moisture content of CMM and decoction shall be controlled between 7 % and 13 %.

Note 2 to entry: This definition is taken from Reference [22].

3.2.10
ash content
basic *purity* (3.2.12) indicator for the quality control of *decoction pieces* (3.2.3)

Note 1 to entry: Ash is present in the residue weight of decoction pieces left after incineration at high temperature (500 ℃ to 600 ℃).

Note 2 to entry: Ash content including physiological ash and acid incompatibility ash.

EXAMPLE The total ash content of GLYCYRRHIZAE RADIX ET RHIZOMA (Gancao) is not more than 7 %. The acid incompatibility ash content is not more than 2 %.

Note 3 to entry: This definition is taken from Reference [22].

3.2.11
texture

shape, size, colour, quality of the herb and *decoction pieces* (3.2.3)

Note 1 to entry: This definition is taken from Reference [23].

3.2.12
purity
quota of the impurities or non-medicinal parts in processed *Chinese materia medica* (3.2.2)

Note 1 to entry: This definition is taken from Reference [22].

3.2.13
pressure
exertion of force upon a surface

3.2.14
decoction ingredient
chemical components including bioactive or therapeutic agents, and other invalid chemical constituents in *decoction pieces* (3.2.3) which stem from *botanical medicine* (3.2.16), *mineral medicine* (3.2.17) and *animal medicine* (3.2.15)

Note 1 to entry: This definition is taken from Reference [25].

3.2.15
animal medicine
Chinese materia medica (3.2.2) derived from animals

Note 1 to entry: Terrestrial animals, insects, marine creatures, organs, tissue, secretion, discharge, glue, solid particles formed in the organs, shell can also be used as CMM.

EXAMPLE PHERETIMA (Dilong), BOVISC ALCULUS (Niuhuang).

