TECHNICAL SPECIFICATION

ISO/TS 23303

First edition
2020-01

Health informatics — Categorial structure for Chinese materia medica products manufacturing process

Reference number
ISO/TS 23303:2020(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 ..... **iv**
Introduction ..... **v**
1 Scope **1**
2 Normative references **1**
3 Terms and definitions **1**
3.1 General 1
3.2 Characterizing categories 2
4 Categorial structure **5**
4.1 Overview 5
4.2 Semantic link 6
4.2.1 Use 6
4.2.2 Is processed by 6
4.2.3 Produce 6
4.2.4 Precede 7
4.2.5 Affect 7
4.2.6 Result in 7
4.2.7 Enhance 7
4.2.8 Reduce 7
Bibliography **8**

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.

The manufacturing process of traditional Chinese materia medica products is a complicated control system engineering including equipment, technology and quality. The manufacturing process proposed in this document is a part of traditional Chinese materia medica control system engineering.

There are many types of manufacturing process, but systematic terminology definitions and semantic links did not exist, which often caused difficulties for production management and metadata analysis.

This arises from two reasons: firstly, a wide variety of dosage forms and manufacturing process are difficult to classify accurately; secondly, the categorial structure of processing Chinese materia medica has not been published.

This document provides a categorial structure which could solve these problems and improve the scientific level of production management of Chinese medicines.

Health informatics — Categorial structure for Chinese materia medica products manufacturing process

1 Scope

This document specifies the whole manufacturing process of Chinese materia medica products by defining a set of domain constraints of sanctioned characteristics, each composed of a relationship and an applicable categorial structure. It includes three process categories: processing, extracting and preparation.

This document is not applicable to Japanese traditional KAMPO medicinal products.

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
unit of knowledge created by a unique combination of *characteristics* (3.1.4)

Note 1 to entry: A concept can have one or more names. It can be represented using one or more terms, pictures, icons or sounds.

3.1.2
category
division of sets of entities regarded as having particular shared *characteristics* (3.1.4)

EXAMPLE Freeze drying, spray drying and all other drying share characteristics particular to the category drying.

Note 1 to entry: Categories can be more or less general. Where one category is subsumed by another, there is a relation asserted to obtain a hierarchy between the more specific or subsumed category and the more general or subsuming category. For example, parenteral route is more general than intravenous route.

3.1.3
categorial structure
minimal set of domain constraints for representing concept systems in a subject field

3.1.4
characteristic
abstraction of a property, of an object or of a set of objects

EXAMPLE Fever is a characteristic symptom of flu.

Note 1 to entry: Characteristics are used for describing concepts and for differentiating categories.

3.1.5
semantic link
formal representation of a directed associative relation or partitive relation between two *concepts* (3.1.1)

Note 1 to entry: This includes all relations except the generic relation.

Note 2 to entry: A semantic link always has an inverse, i.e. another semantic link with the opposite direction.

[SOURCE: ISO 17115:2007, 2.2.3, modified — Note 3 to entry was removed.]

3.1.6
Chinese medicines
substance or combination of substances used under the guidance of traditional Chinese medicine theory for medical care and the prevention and treatment of disease

Note 1 to entry: This includes Chinese materia medica, decoction pieces, Granule Forms of Individual Medicinals for Prescriptions (GFIMP), and Chinese Patent Medicines (CPM).

[SOURCE: ISO 20333:2017, 3.1]

3.1.7
manufacturing
complete process of production through all processing stages, including final packaging, and all materials involved in the process

3.1.8
product
thing or material manufactured from all processing stages of *manufacturing* (3.1.7)

Note 1 to entry: Chinese materia medica manufacturing products include, but are not limited to, decoction pieces, extraction (includes two categories: monomer and mixture), Chinese patent medecine.

3.2 Characterizing categories

3.2.1
Chinese materia medica
CMM
medicinal parts of medicinal plants, animals, and minerals used as raw materials in *Chinese medicines* (3.1.6) after preliminary *processing* (3.2.6)

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

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

Note 2 to entry: Preliminary processing refers to some operations in the process of harvesting Chinese materia medica, such as removing sundries, sorting, packing, etc. for better storage and management.

3.2.2
origin
location of *Chinese materia medica* (3.2.1)

EXAMPLE The places where the plants were grown, Dangshen origin: ShanXi.

3.2.3
variety
class of Chinese materia medica divided according to its own *characteristics* (3.1.4)

EXAMPLE Liquorice has variety types, such as raw liquorice and moxibustion liquorice.

Note 1 to entry: Decoction pieces can be divided into pieces, segments, silk and slices according to different shape.

3.2.4
decoction piece
prescription medicinal processed from *Chinese materia medica* (3.2.1) under the guidance of traditional Chinese medicine and *processing methods* (3.2.7) for *Chinese medicines* (3.1.6)

[SOURCE: ISO 18668-1:2016, 3.3, modified]

3.2.5
description
shape, size, colour, odour, etc. of the *decoction piece* (3.2.4) and *adjuvant material* (3.2.8)

3.2.6
processing
action of performing, for pharmaceutical purposes, a series of mechanical or chemical operations to change or preserve *Chinese materia medica* (3.2.1) according to Chinese medicine theory, the nature of herbs, and the medical and pharmaceutical needs

Note 1 to entry: Chinese materia medica can be processed using, for example, water or fire processing. Adjuvant material, instruments, heat can also be used to produce decoction pieces. Through processing, the effectiveness of Chinese materia medica can be enhanced and the toxicity and odour of Chinese materia medica can be reduced.

3.2.7
processing method
method used to change the nature of *Chinese materia medica* (3.2.1)

EXAMPLE Calcine and roast are two methods used to process Chinese materia medica.

3.2.8
adjuvant material
substance added during the *processing* (3.2.6) of *Chinese materia medica* (3.2.1) to enhance the therapeutic usefulness of pharmaceutical herbal treatment

[SOURCE: ISO/TS 18062:2016, modified]

3.2.9
purifying
process of eliminating impurities and removing non-medical parts

3.2.10
effectiveness
therapeutic results of a *processing method* (3.2.7)

EXAMPLE Ephedra has improved effectiveness in antitussive, expectorant and other effects through the processing of honey.

3.2.11
toxicity
degree to which a *Chinese materia medica* (3.2.1) can cause harm, injury or death

EXAMPLE Through heating processing, toxic alkaloids in aconite can degrade and reduce toxicity.

3.2.12
extracting
process of obtaining effective or active ingredients from raw materials

EXAMPLE Ginkgo flavone is extracted from ginkgo leaves.

3.2.13
leaching
process of getting a soluble material from an insoluble solid by using a solvent

EXAMPLE The leaching of Chinese materia medica includes decocting, steam distillation, etc.

Note 1 to entry: This definition is taken from Reference [9].

3.2.14
separating
division and parting of materials into their constituent parts

EXAMPLE Macroporous resin separation and membrane separation are two modern methods for separating effective constituents.

Note 1 to entry: Separating is used for purification by removing contaminants, or for enrichment.

Note 2 to entry: This definition is taken from Reference [8].

3.2.15
concentrating
process during which solvent evaporates, which increases the concentration of the solution

EXAMPLE Concentration under reduced pressure and film concentration are two methods for concentrating intermedia object.

3.2.16
drying
vaporizing water or other solvents from liquid materials by using heat energy

EXAMPLE Vacuum drying; spray drying are two commonly used methods for drying.

Note 1 to entry: This definition is taken from Reference [9].

3.2.17
refining
purifying (3.2.9) impure materials without producing a chemical change

Note 1 to entry: This definition is taken from Reference [9].

3.2.18
extractive
single component or mixed component having a definite index component extracted from *Chinese materia medica* (3.2.1) by a suitable method

EXAMPLE Jin Qing extract is a kind of extractive made from Ginkgo and Artemisia.

3.2.19
monomer
substance having only one component

3.2.20
mixture
combination of two or more different substances

3.2.21
preparation
process of transforming an active pharmaceutical ingredient into a certain *dose form* (3.2.26)

EXAMPLE Ginkgo flavone is prepared into tablets by adding a certain amount of adjuvant material to it.

Note 1 to entry: This can be used directly for the operation of clinical drugs.

3.2.22
pulverizing
process of reducing large pieces of solid material to the size of fragments or to fine powder using the mechanical force

3.2.23
blending
mixing of two or more materials together

Note 1 to entry: Blending is a process used to obtain a blended result with specific properties.

3.2.24
forming
result of crafting into *Chinese patent drug* (3.2.25) (with physical and chemical properties) for clinical application

3.2.25
Chinese patent drug
Chinese patent medicine
class of drugs made from raw material under the guidance of Chinese medicine theory, according to the provisions of the prescription and methods of *processing* (3.2.6)

Note 1 to entry: Chinese patent drugs are used for clinical treatment or prevention of adverse health problems.

3.2.26
dose form
dosage form
physical manifestation of a medicinal product that contains the active ingredient(s) and/or inactive ingredient(s) that are intended to be delivered to the patient

Note 1 to entry: 'Pharmaceutical dose form' can refer to the administered dose form or the manufactured dose form.

[SOURCE: ISO 11615:2017, 3.1.24, modified]

Note 2 to entry: Tablet, granule and capsule are the most common dose forms.

3.2.27
dose
dosage
measured quantity of a medicine to be taken

Note 1 to entry: This definition is taken from Reference [10].

4 Categorial structure

4.1 Overview

The formal concept representation system in the field of decoction includes characterizing categories (see 3.2) and semantic links (see 4.2).

The outline of those characterizing categories and semantic links is illustrated in a concept diagram shown in Figure 1.

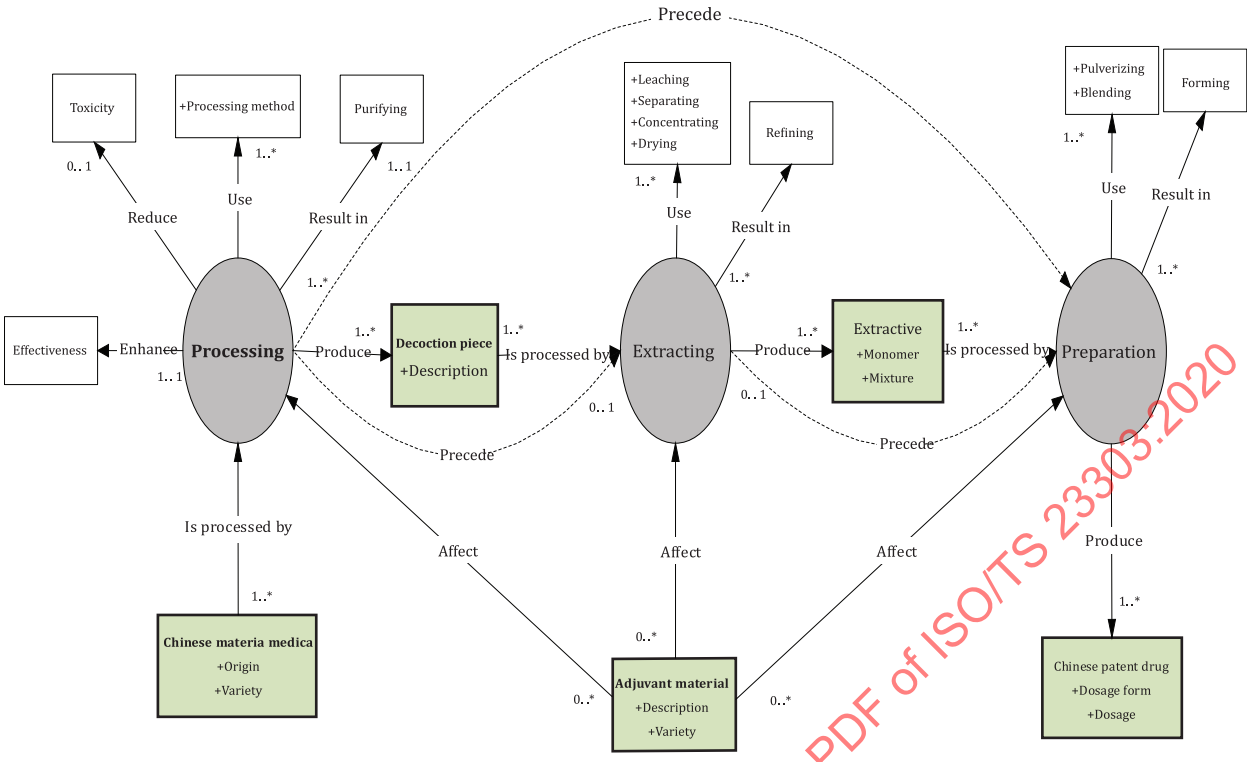

Figure 1 — Categorial structure for the manufacturing process of Chinese materia medica products

4.2 Semantic link

4.2.1 Use

Employ for some purpose; put into service; make use of.

It expresses the semantic link between extracting (see 3.2.12) and leaching (see 3.2.13), between processing (see 3.2.6) and processing method (see 3.2.7), and between preparation (see 3.2.21) and pulverizing (see 3.2.22).

EXAMPLE <The extraction process of ginkgo extract> uses <'leaching', 'separating','concentrating' and 'drying'>.

NOTE It includes applies, utilizes, and avails, as well as additions of certain adjuvant materials.

4.2.2 Is processed by

Chinese materia medica being treated by a particular series of actions in manufacturing.

It expresses the semantic link between Chinese materia medica (see 3.2.1) and processing (see 3.2.6), decoction piece (see 3.2.4) and extracting (see 3.2.12), extractive (see 3.2.18) and preparation (see 3.2.21).

EXAMPLE <A Gecko is processed> by <cutting the head, feet and scales>.

4.2.3 Produce

Relationship between the maker of a product and the product indicating the act of making that product.

