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

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Foreword

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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.