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Health informatics — Information model for quality control of traditional Chinese medicinal products

Informatique de santé — Modèle d'information pour le contrôle de la qualité des médicaments traditionnels chinois

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Foreword

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This document was prepared by Technical Committee ISO/TC 215, *Health informatics,* in collaboration with Technical Committee ISO/TC 249, *Traditional Chinese medicine*.

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, especially traditional Chinese medicinal products are widely utilized as a part of complementary and alternative medicine throughout East Asia and western countries. In order to guarantee quality and therapeutic effects, quality control of traditional Chinese medicinal products is very significant and valuable.

Quality control of traditional Chinese medicinal products is very difficult. This is due to five main reasons: firstly, a wide variety of dosage forms and the manufacturing processes are difficult to accurately classify; secondly, the influencing factors in the manufacturing process are very complicated, which are difficult to be accurately described and controlled; thirdly, an information model of the preparation of Chinese materia medica has not been described and published; fourthly, the therapeutic effect of Chinese medicine is the comprehensive result of multi-component material based on biological metabolism engineering, and the quality control technology of Chinese medicine is often unable to meet the practical needs due to its complex mechanism; fifthly, the requirements for quality control of traditional Chinese medicinal products and relevant regulations vary greatly from country to country, resulting in various and inconsistent standards for traditional Chinese medicinal products and the inability to achieve drug circulation and resource sharing.

The wide range of disciplines and the specific national usages have led to different meanings being attributed to particular terms and different terms being used to describe the same concept. To avoid the consequent misunderstandings and to facilitate the exchange of information, it is essential to clarify the concepts, to establish the correct terms for use, and to establish their definitions.

Health informatics — Information model for quality control of traditional Chinese medicinal products

1 Scope

This document specifies an information model representing the quality control of the manufacturing process of traditional Chinese medicinal products by defining a set of domain constraints of sanctioned characteristics, each composed of a relationship.

It is applicable to the quality supervision and management of manufacturing process of Chinese materia medica.

Japanese KAMPO medicine is outside the scope of this document.

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 terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

3.1 General

3.1.1
concept
unit of knowledge created by a unique combination of characteristics

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

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, a relation is 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
information model
graphical and textual representation of entities and the relationships 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]

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

EXAMPLE Fever is a characteristic symptom of the flu.

Note 1 to entry: Characteristics are used for describing *concepts* (3.1.1) and for differentiating *categories* (3.1.2).

3.1.5
semantic link
formal representation of a directed associative relation or partitive relation between two concepts

EXAMPLE Is cause of (with inverse has cause); has Location (with inverse is Location Of).

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 17115:2020, 3.2.5, modified — Example has been changed.]

3.1.6
Chinese medicine
substance or combination of substances used under the guidance of traditional Chinese medicine (TCM) 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 18668-1:2016, 3.1]

3.2 Characterizing categories

3.2.1
chemical analysis
qualitative and quantitative analysis based on the chemical reactions of substances

EXAMPLE HPLC, MS, NMR, IR, UV, GC, CE and other combined techniques were used for the quantitative determination of active ingredients or index components

3.2.2
bioanalysis
analysis of the biological activity (including efficacy and toxicity) of drugs using organisms including whole animals, in vitro tissues, organs, cells and microorganisms

3.2.3
character analysis
simple physical and chemical test method used to distinguish the true and the false by the apparent characters of the objects

3.2.4
impurity
substance that has no therapeutic effect or damages to the body

3.2.5
effective constituent
chemical constituents of Chinese materia medica, intermediates and Chinese patent medicine that are efficacious

3.2.6
endogenous toxic component
substance in medicine that causes adverse effects and damage to the body

3.2.7
exogenous harmful substance
harmful ingredients in medicine including pesticide residue, heavy metals, etc.

3.2.8
heavy metal
metal usually of relatively high density, atomic weight, or atomic number

Note 1 to entry: In metallurgy, for example, a heavy metal can be defined on the basis of density, whereas in physics, the distinguishing criterion can be the atomic number, while a chemist would likely be more concerned with chemical behaviour. More specific definitions have been published, but none of these have been widely accepted. A density of more than 5 g/cm3 is sometimes quoted as a commonly used criterion.

EXAMPLE Pb, Hg, Bi, As, Ti, Sn, Cd, Ag, Cu and Mo.

3.2.9
pesticide residue
chemical agent that remains in organisms, harvests, soil, water, pesticide progenitor in the atmosphere, toxic metabolites, degradation products and impurities

3.2.10
microbiological detection
process of active data-gathering with appropriate analysis and interpretation of biosphere data that can relate to disease activity and threats to human or animal health – whether infectious, toxic, metabolic, or otherwise, and regardless of intentional or natural origin – in order to achieve early warning of health threats, early detection of health events, and overall situational awareness of disease activity

3.2.11
index
standard by which the level of something can be judged or measured

3.2.12
active ingredient
chemical or biological component that is included in the formulation of a health care product to achieve the intended purpose

3.2.13
moisture content
ratio of the mass of the quantity of water in a material to the mass of the dry material

[SOURCE: ISO 15206:2010, 3.24]

3.2.14
ash content
measure of the total amount of minerals present within traditional Chinese medicinal products

3.2.15
residual solvent
chemicals that pharmaceutical companies use to manufacture different prescription drugs

Note 1 to entry: They have various degrees of toxicity that are classified according to three levels. In order to adhere to national safety guidelines and ethics regarding human exposure to chemicals, manufacturers can only allow certain levels of solvents to remain in their finished products

3.2.16
pH value
measure of the concentration of acidity or alkalinity of a material in an aqueous solution

Note 1 to entry: The pH value is expressed on a logarithmic scale numbered from 0 to 14 with 7,0 as a neutral point, numbers higher than 7 denoting alkalinity and numbers lower than 7 denoting acidity.

[SOURCE: ISO 5127:2017, 3.12.2.29, modified — Note 2 to entry deleted.]

3.2.17
fingerprint
chromatogram that can identify the chemical characteristics of CMM, decoction piece, extractive and traditional Chinese medicinal products

Note 1 to entry: It is a comprehensive and quantifiable identification method, which is based on the systematic study of the chemical components of traditional Chinese medicine, and mainly used to evaluate the authenticity, superiority and stability of the quality of Chinese materia medica and semi-finished Chinese medicine products.

Note 2 to entry: Chinese medicine fingerprint technique has involved many methods, HPLC, TLCS and GC have been recognized as three conventional analytical methods.

3.2.18
Chinese materia medica
CMM
medicinal parts of medicinal plants, animals, and minerals after preliminary processing, 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]

3.2.19
decoction piece
prescription medicinal processed from Chinese materia medica under the guidance of traditional Chinese medicine and processing methods for Chinese medicines

[SOURCE: ISO 18668-1:2016, 3.3, modified — Note 2 to entry deleted.]

3.2.20
extractive
single component or mixed component having a definite index component extracted from Chinese materia medica by a suitable method

EXAMPLE Flow dip powder, fluid extract.

3.2.21
traditional Chinese medicinal products
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

Note 1 to entry: Traditional Chinese medicinal products are used for clinical treatment or prevention of adverse health problems.

3.2.22
quality
essential identifying nature or character of somebody or something

3.2.23
formula
prescription of dispensing decoction pieces or active pharmaceutical ingredients (API) according to certain methods or rules

[SOURCE: WHO Western Pacific Region, 2007[7]]

3.2.24
prescription dosage
quantity of each tablet in the formula issued by a Chinese medicine physician

3.2.25
production
act of manufacturing pharmaceutical goods

3.2.26
equipment
machinery, tools, etc. needed to complete drug production

3.2.27
critical process parameter
process parameter whose variability has an impact on a critical quality attribute and therefore needs to be monitored or controlled to ensure the process produces the desired quality

Note 1 to entry: A manufacturing parameter is considered "critical" and necessary for production of Substance or Specified Substance e.g. inclusion of chromatographic step for removal or reduction of impurities, viruses etc.

Note 2 to entry: The critical process is tied to the Production Method type.

[SOURCE: ISO 11238:2018, 3.20]

3.2.28
adjuvant material
substance added during processing in order to enhance the therapeutic usefulness of pharmaceutical herbal medicament treatment

Note 1 to entry: "Adjuvant" in this context does not mean the adjuvant in modern scientific parlance, rather, is used to support elution of bioactive substrates, enhancing efficacy and reducing toxicity, flavouring and taste masking, or as a filler.

EXAMPLE Rice wine, liquor, vinegar, honey.

[SOURCE: ISO/TS 18062:2016, 3.4]

3.2.29
environment
surroundings in which an organization operates, including air, water, land, natural resources, flora, fauna, humans and their interrelationships

[SOURCE: ISO 14001:2015, 3.2.1, modified — Notes removed.]

3.2.30
storage
complete process of production from the acquisition of all materials through all processing stages and including final packaging

3.2.31
efficacy
effect of drugs on the prevention and treatment of disease under prescribed indications, dosage and administration

Note 1 to entry: See ICH (International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use) efficacy guidelines[13].

3.2.32
safety
extent to which a Chinese medicine produces a toxic side effect under prescribed indications and dosage and administration

Note 1 to entry: See ICH safety guidelines[14].

3.2.33
stability
ability of a drug to maintain physical, chemical, biological and microbial characteristics

Note 1 to entry: See ICH guidelines[15].

3.2.34
quality control
part of quality management focused on fulfilling quality requirements

Note 1 to entry: The quality control of traditional Chinese medicinal products includes both efficacy, safety and stability.

[SOURCE: ISO 9000:2015, 3.3.7, modified — Note to entry added.]

4 Categorial structure

4.1 Information model for quality control of traditional Chinese medicinal products

The representation system of the formal concepts pertaining to the quality control of traditional Chinese medicinal products includes characterizing categories (see 3.2) and semantic links (see 4.2). It is illustrated in Figure 1 as an information model.

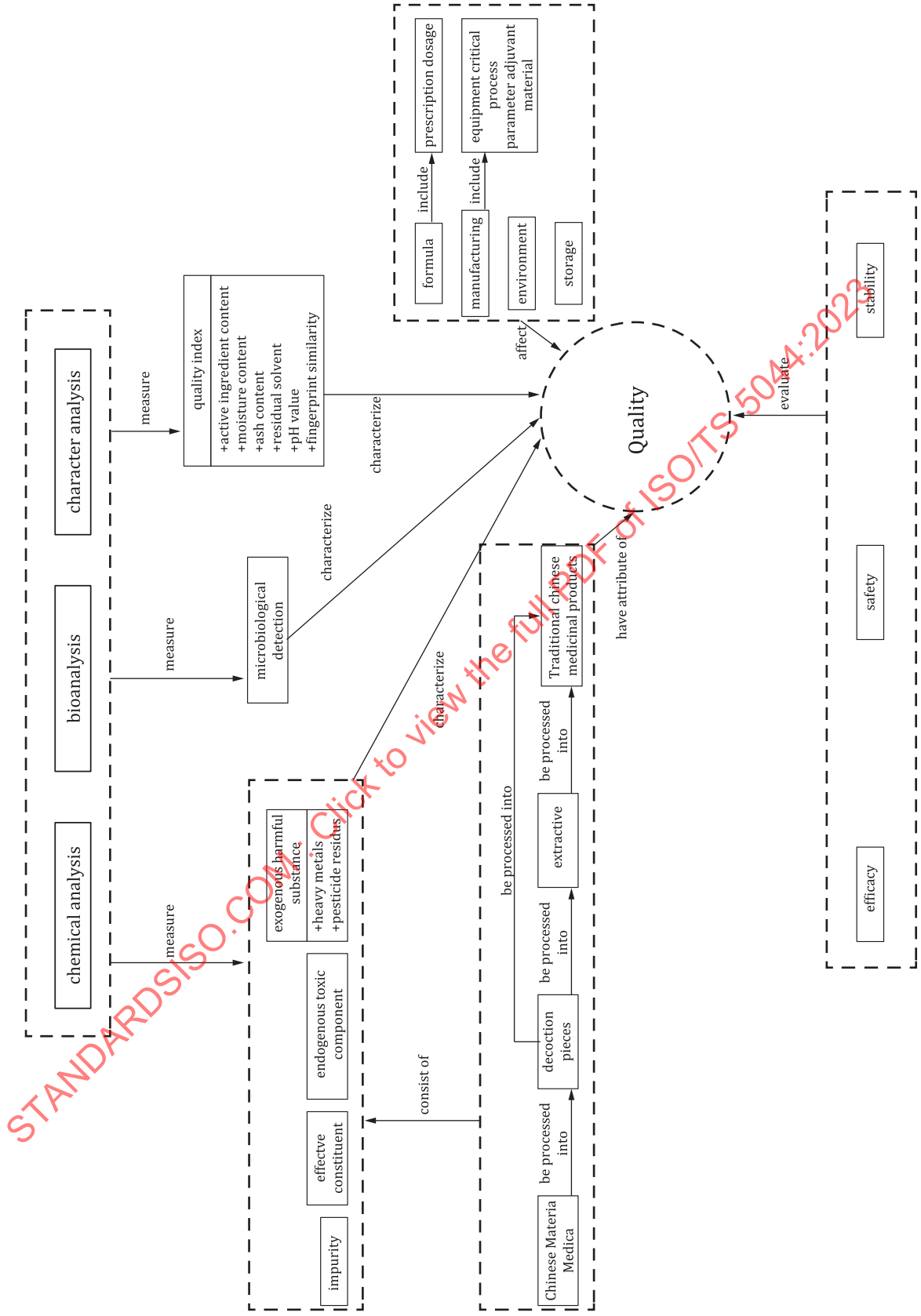

Figure 1 — Information model for quality control of traditional Chinese medicinal products

4.2 Semantic link

4.2.1 measure

a way of achieving something, or a method for dealing with a situation

Semantic links: Between chemical analysis (see 3.2.1) and component (see 3.2.4), bioanalysis (see 3.2.2) and microbiological detection (see 3.2.11), character analysis (see 3.2.3) and quality index (see 3.2.12).

4.2.2 consist of

indicates the relationship between things and their components

Semantic links: Between CMM (see 3.2.21), decoction piece (see 3.2.22), extractive (see 3.2.23), traditional Chinese medicinal products (see 3.2.24) and effective constituent (see 3.2.6), impurity (see 3.2.5), endogenous toxic component (see 3.2.7), exogenous harmful substance (see 3.2.8).

4.2.3 characterize

to describe something by stating its main qualities

Semantic links: Between quality (see 3.2.25) and component (see 3.2.4), microbiological detection (see 3.2.11), quality index (see 3.2.12).

4.2.4 affect

produces a direct effect on

Implied here is the altering or influencing of an existing condition, state, situation, or entity. This includes alters, influences, predisposes, catalyzes, stimulates, regulates, depresses, impedes, enhances, contributes to, leads to, and modifies.

Semantic links: Between quality index (see 3.2.12) and formula (see 3.2.26), production (see 3.2.28), environment (see 3.2.32), storage (see 3.2.33).

4.2.5 be processed into

treated or prepared using a special process

Semantic links: Between CMM (see 3.2.21) and decoction piece (see 3.2.22), extractive (see 3.2.23), traditional Chinese medicinal products (see 3.2.24).

4.2.6 have attribute of

a quality or characteristic that someone or something has

Semantic links: Between CMM (see 3.2.21), decoction piece (see 3.2.22), extractive (see 3.2.23), traditional Chinese medicinal products (see 3.2.24) and quality (see 3.2.25).

4.2.7 include

to contain someone or something as a part

Semantic links: Between formula (see 3.2.26) and prescription dosage (see 3.2.27), production (see 3.2.28) and equipment (see 3.2.29), critical process parameter (see 3.2.30), adjuvant material (see 3.2.31).