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Traditional Chinese medicine — Coding system of formulae

Médecine traditionnelle chinoise — Système de codification des formules

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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).

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For an explanation on 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 the following URL: www.iso.org/iso/foreword.html.

This document was prepared by ISO/TC 249, *Traditional Chinese medicine*.

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Introduction

The botanical market has great potential; botanical research has been highly regarded and Chinese medicines are gradually becoming increasingly recognized and approved in international markets. Many countries have achieved remarkable success in the exploitation of Chinese medicines, including the application of alternative therapies and the search for pharmaceutical sources. More and more countries are becoming involved in the Chinese medicines trade. At present, the annual sale of Chinese medicines has reached more than USD 16 billion, and is increasing at a rate of 10 % to 20 % per year. More than 70 countries have established Chinese medicines regulations. Many countries are developing traditional medicine vigorously, which brings more opportunities for trade and exchange in Chinese medicines.

The purpose of this document is to:

1) specify coding rules for formulae, identify 1 233 formulae, ensure safe and effective application of formulae;

2) assist practitioners to use formulae correctly, and promote standardization, normalization and informatization of formula administration;

3) promote the wide application of TCM electronic medical records and prescriptions;

4) enable source-tracing and controllability of electronic medical records and prescriptions in procedures of diagnosis and prescribing, in order to build a more fair and transparent information system;

5) expand the international academic exchange of formulae, and provide technical support for the standardization of prescribing;

6) help different countries to establish a standard management system of formulae and Chinese medicine prescriptions, aiming to make the application and management of formulae more effective, safeguard the vital interests of patients, and promote sustainable development of the whole industry.

This document specifies rules to encode formulae, and gives specific codes for 1 233 frequently-used Formulae (1 165 formulae in Annex B and 68 formulae in Annex C). The criteria for selecting the formulae are:

— classic works, such as The Inner Canon of Huangdi (黃帝內經)[93], Treatise on cold (傷寒論)[131], Synopsis of Golden Chamber (金匱要略)[98], treatise on differentiation and treatment of epidemic febrile disease (溫病條辨)[164], and Chinese pharmacopoeia[9][10];

— experts' manuals for tertiary and second-class hospitals' evaluation of hospital management by TCM State Chinese Medicine Administration Bureau[13][14];

— the Acupuncture and Chinese medicine practitioners' qualification exam guide of the United States (Chinese and English)[61];

— national project textbooks of Chinese medicine (Version 9): Chinese internal medicine, Surgery of Chinese medicine, Chinese paediatrics, Chinese gynaecology, and formulae of Chinese medicine[33][34][35][36][37];

— a complete collection of Chinese famous doctors' Formulae (9031 in total), Traditional Chinese formula dictionary (11 volumes in total), and Traditional Chinese medicine dictionary[63].

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Traditional Chinese Medicine — Coding system of formulae

1 Scope

This document specifies rules to encode formulae, and gives specific codes for 1 233 frequently-used formulae. Chinese patent medicines (CPM) are outside the scope of this document. Kampo formulae are outside of the scope of this document.

This document is applicable to formula-relating databases in fields of clinical medication, scientific research and teaching, electronic medical records and prescription of traditional Chinese medicine (TCM).

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/IEC 15420, *Information technology — Automatic identification and data capture techniques — EAN/UPC bar code symbology specification*

ISO 18668-1:2016, *Traditional Chinese medicine — Coding system for Chinese medicines — Part 1: Coding rules for Chinese medicines*

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
formula
TCM formula
specified prescriptions and preparations which consist of certain kinds of Chinese medicines based on pattern differentiation, disease differentiation, and treatment methods of traditional Chinese medicine, by principles of formulating prescriptions and structure

3.2
layer
code layer
set of the characters within the code

EXAMPLE A sub-field within the code.

[SOURCE: ISO 18668-1:2016, 3.5, modified]

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3.3
Four-Constitution Medicine
Sasang Constitutional Medicine
medicine initiated by Lee Je-ma, which stresses the theory of the four constitutions: physiology, pathology, diagnosis, and maintenance of health

[SOURCE: World Health Organization 2007: *WHO International Standard Terminologies on Traditional Medicine in the Western Pacific Region*, 0.0.33]

3.4
greater yang person
Tae-yang person
Tai-yang person
one who has strong lung and weak liver in the context of Four-Constitution Medicine

[SOURCE: World Health Organization 2007: *WHO International Standard Terminologies on Traditional Medicine in the Western Pacific Region*, 0.0.35]

3.5
lesser yang person
So-yang person
Shao-yang person
one who has strong spleen and weak kidney in the context of Four-Constitution Medicine

[SOURCE: World Health Organization 2007: *WHO International Standard Terminologies on Traditional Medicine in the Western Pacific Region*, 0.0.36]

3.6
greater yin person
Tae-eum person
Tai-yin person
one who has strong liver and weak lung in the context of Four-Constitution Medicine

[SOURCE: World Health Organization 2007: *WHO International Standard Terminologies on Traditional Medicine in the Western Pacific Region*, 0.0.37]

3.7
lesser yin person
So-eum person
Shao-yin person
one who has strong kidney and weak spleen in the context of Four-Constitution Medicine

[SOURCE: World Health Organization 2007: *WHO International Standard Terminologies on Traditional Medicine in the Western Pacific Region*, 0.0.38]

4 Coding principles

4.1 Uniqueness

Each formula corresponds to a unique code.

4.2 Scalability

The coding rules allow sufficient space for expansion.

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