INTERNATIONAL STANDARD

ISO 20334

First edition 2018-06

Traditional Chinese medicine — Coding system of formulae

Médecine traditionnelle chinoise — Système de codification des formules

iTeh STANDARD PREVIEW (standards.iteh.ai)

ISO 20334:2018 https://standards.iteh.ai/catalog/standards/sist/d09d7821-eaad-4807-b10d-6ba8cf4d2f56/iso-20334-2018



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Published in Switzerland

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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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6ba8cf4d2f56/iso-20334-2018

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

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;

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- 5) expand the international academic exchange of formulae, and provide technical support for the standardization of prescribing: ai/catalog/standards/sist/d09d7821-eaad-4807-b10d-6ba8cf4d2f56/iso-20334-2018
- 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 34 Coding system for Chinese medicines — Part 1: Coding rules for Chinese medicines — Part 1: Coding rules for Chinese medicines — Chinese medicines — Part 1: Coding rules for Chinese medicines — Par

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

laver

code layer

set of the characters within the code

EXAMPLE A sub-field within the code.

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

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, 0.036] ndards.iteh.ai)

3.6 <u>ISO 20334:2018</u>

greater yin person

https://standards.iteh.ai/catalog/standards/sist/d09d7821-eaad-4807-b10d-

Tae-eum person 6ba8cf4d2f56/iso-20334-2018

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.

4.3 Stability

The code for each formula remains unchanged once assigned, as long as the basic characteristic of the formula does not change. Even if some formulae are discontinued for use, their codes should still be kept.

5 Coding technology

5.1 Structure

Formulae are classified according to action. The structure consists of seven layers, with 10 Arabic digits in total, as shown in Figure 1.

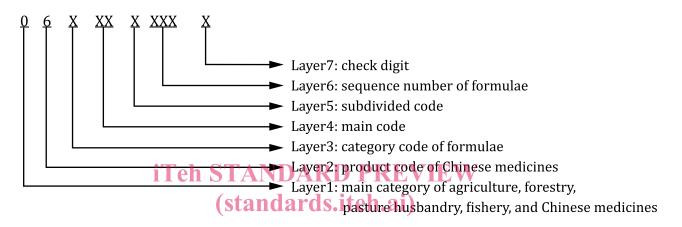


Figure 1 — Coding structure of formulae https://standards.iich.ai/catalog/standards/sist/d09d7821-eaad-4807-b10d-6ba8cf4d2f56/iso-20334-2018

5.2 Detailed description

5.2.1 Layer 1

Layer 1 is in categories of agriculture, forestry, pasture husbandry, fishery and Chinese medicines; formulae belong to Chinese medicine, symbolized by "0", in accordance with ISO 18668-1.

5.2.2 Layer 2

Layer 2, the product code of Chinese medicines, is symbolized by "6", in accordance with ISO 18668-1.

5.2.3 Layer 3

Layer 3, the category code of formulae, is a special code for formula, symbolized by "0".

5.2.4 Layer 4

Layer 4, the main code, is symbolized by two digits. The most frequently-used efficacy are selected as the basis for formula classification. Main codes from "01" to "20" are traditionally classified into 20 categories as exterior-releasing formulae, purgative formulae, harmonizing and releasing formulae and so on. In addition, main codes from "41" to "44" are classified into 4 categories as Sasang constitution. See Table 1 for details.

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5.2.5 Layer 5

Layer 5, the subdivided code, is a secondary classification under the main code of action, symbolized by one digit. For example, exterior-releasing formulae are classified as pungent-warm exterior-releasing formulae, pungent-cool exterior releasing formulae, healthy-qi-reinforcing and exterior-releasing formulae, and exterior-interior-releasing formulae. There are 68 secondary classifications in total. See Table 1 for details.

5.2.6 Layer 6

Layer 6, the sequence number of formulae, symbolized by three digits, is the order number of the formulae located in the code table. Take Ephedra decoction for example, "001" indicates that Ephedra decoction is the first kind of pungent-warm exterior releasing formula in Table B.1.

5.2.7 Layer 7

Layer 7, the check digit, symbolized by one digit from "0" to "9", is calculated by the method in ISO/IEC 15420. See Annex A for details.

Table 1 — Formula category code

Category	Main category of formula	Code (layer 4)	Subdivided category of formula	Code (layer 5)
	iTeh STA	NDAR 1dards 01 ISO 20334:2 alog/standards/s	Pungent-warm exterior-releasing formula	1
	Exterior-releasing formula https://standards.iteh.ai/cata		Pungent-cool exterior-releasing formula	2
			releasing formula 1807-b10d-	3
	6ba8		0334-2018 Exterior-interior-releasing formula	4
	Purgative formula	02	Cold purgative formula	1
			Warm purgative formula	2
			Lubricant laxative formula	3
			Water-expelling formula	4
Action category			Offensive purgative and healthy-qi-reinforcing formula	5
	Harmonizing and releasing formula	03	Lesser-yang-harmonizing formula	1
			Liver-spleen-harmonizing formula	2
			Gastrointestine-harmonizing formula	3
	Heat-clearing formula	04	Qi-aspect-clearing formula	1
			Nutrient-aspect-clearing and blood-cooling formula	2
			Heat-clearing and detoxicating formula	3
			Bowel and visceral heat-clearing formula	4
			Deficiency heat-clearing formula	5

Category	Main category of formula	Code (layer 4)	Subdivided category of formula	Code (layer 5)		
	Summerheat-dispelling formula	05	Summerheat-dispelling formula	1		
	Interior-warming formula	06	Middle-warming and cold- dispelling formula	1		
			Yang-returning and counterflow- stemming formula	2		
			Meridian-warming and cold- dissipating formula	3		
			Qi-tonifying formula	1		
			Blood-tonifying formula	2		
	T: C-: C	07	Qi-blood-tonifying formula	3		
	Tonifying formula	07	Yin-tonifying formula	4		
			Yang-tonifying formula	5		
			Yin-yang-tonifying formula	6		
	iTeh STANDA (standard Securing and astringent formula ISO 203 https://standards.iteh.ai/catalog/standard 6ba8cf4d2f56/is	RD Pl ds.iteh 08 0334:2018 dards/sist/d09d	Exterior-securing anhidrotic formula	1		
			Lung-constraining and cough- suppressing formula	2		
			Intestines-astringing and collapse- relieving formula	3		
			Essence-astringing and emission and enuresis-checking formula	4		
			Flooding-stemming and discharge- checking formula	5		
		09	Settling tranquillizing formula	1		
	Tranquillizing formula		Enriching and nourishing tranquillizing formula	2		
		1.0	Cool orifice-opening formula	1		
	Orifice-opening formula	10	Warm orifice-opening formula	2		
	Qi-regulating formula	4.4	Qi-moving formula	1		
		11	Qi-descending formula	2		
	Blood-regulating formula	12	Blood-activating and stasis- dispelling formula	1		
	Dioou-regulating for mula		Hemostatic formula	2		
	Wind-treating formula		External-wind-dispersing formula	1		
		13	Internal-wind- extinguishing formula	2		
			External-dryness-diffusing formula	1		
	Dryness-treating formula	14	Yin-enriching and dryness- moistening formula	2		

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Category	Main category of formula	Code (layer 4)	Subdivided category of formula	Code (layer 5)	
		15	Dampness-drying and stomach- harmonizing formula	1	
	Dampness-dispelling formula		Heat-clearing and dampness- dispelling formula	2	
			Dampness-draining diuretic formula	3	
			Cold-dampness warming and resolving formula	4	
			Wind-dispelling and dampness- overcoming formula	5	
			Dampness-drying and phlegm- resolving formula	1	
		16	Heat-clearing and phlegm-resolving formula	2	
	Phlegm-dispelling formula		Dryness-moistening and phlegm-resolving formula	3	
	iTeh STA	NDAR	Cold-phlegm warming and resolving formula	4	
		dards	Phlegm-resolving and wind- extinguishing formula	5	
	Digestant formulaards.iteh.ai/cata	ISO 20334:2 alog/stanzlards/	Digestion-promoting and stagnation-resolving formula	1	
	6ba8	cf4d2f56/iso-2	Spleen-fortifying and digestion- promoting formula	2	
	Worm-expelling formula	18	Worm-expelling formula	1	
	Emetic formula	19	Emetic formula	1	
	Formula for treating abscess	20	Formula of oral administration	1	
	and ulcer	20	Formula of external application	2	
		44	Formula for exterior febrile disease	1	
	Lesser yin person formula	41	Formula for interior cold disease	2	
			Formula for exterior cold disease	1	
Four Constitution	Lesser yang person formula	42	Formula for interior febrile disease	2	
Four-Constitution formula	Cuantan sin nan fl	42	Formula for exterior cold disease	1	
	Greater yin person formula	43	Formula for interior febrile disease	2	
	Greater yang person formula	44	Formula for lumbar verebrae disease	1	
			Formula for small intestine disease	2	

6 Example

Ephedra Decoction, exterior-releasing formula, with the action of releasing exterior with pungent-warm, which contains Ephedra (encoded as 06141050500104003 according to ISO 18668-2), Cinnamon Twig (06154520200103001), Chan Bitter Apricot Seed (06156140600100820), Processed Liquorice Root (06156310300203354), is encoded as "0 6 0 01 1 001 7". The first two numbers "06" in layer 1 and layer 2 represent the product of Chinese medicines; the third number "0" in layer 3 represents formulae; the fourth and fifth number "01" in layer 4 represent exterior-releasing formula; the sixth number "1" in layer 5 represents pungent-warm exterior-releasing formula; the seventh, eighth and ninth number "001" in layer 6 represent the first kind of pungent-warm exterior-releasing formula in the table; check digit "7" is calculated by the method given in ISO/IEC 15420. As shown in Figure 2.

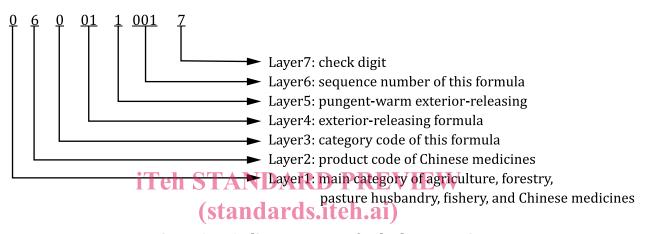


Figure 2 — Coding structure of Ephedra Decoction ISO 203342018

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Annex A

(normative)

Calculation of check digit

A.1 Serial number of code location

This indicates the serial number of the 14 digits from the right to the left, among which the check digit is specified as 1.

A.2 Calculation steps

Calculate the check digit by the method in ISO/IEC 15420.

Calculation steps are shown as follows.

- a) Sum up the digits located below even serial numbers from serial number 2, to get *Result 1*.
- b) Multiply Result 1 by 3 to get Result 2.
- c) Sum up the digits located below odd serial numbers from serial number 3, to get *Result 3*.
- d) Sum up Result 2 and Result 3 to get Result 4.
- e) Substract *Result 4* by a number which is larger or equal to *Result 4*, and also be the smallest multiple of 10, to get the digit of check digit.

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For example, the calculation of code 0600110017 is demonstrated in Table A.1.

Table A.1 — Calculation of check digit

r	I										
Steps	Demonstration										
Number from the right to the left	Serial number	10	9	8	7	6	5	4	3	2	1
	Code	0	6	0	0	1	1	0	0	1	X
a) Sum up the digits located below even serial numbers from serial number 2, to get <i>Result 1</i> .	1 + 0 + 1 + 0 + 0 = 2 (Result 1)										
b) Multiply <i>Result 1</i> by 3 to get <i>Result 2</i> .	$2 \times 3 = 6 (Result 2)$										
c) Sum up the digits located below odd serial numbers from serial number 3, to get <i>Result 3</i> .	0 + 1 + 0 + 6 = 7 (<i>Result 3</i>)										
d) Sum up <i>Result 2</i> and <i>Result 3</i> to get <i>Result 4</i> .	6 + 7 = 13 (<i>Result 4</i>)										
e) Subtract <i>Result 4</i> by a number which is larger or equal to <i>Result 4</i> , and also be the smallest multiple of 10, to get the digit of check digit.	check digit X = 7										

Annex B (normative)

Codes of formulae

NOTE The components of formulae are indicative only and are listed for information and reference purposes. They do not represent an attempt to rigidize the components of formulae. Practitioners can modify the components of formulae according to the patient needs and product availability.

Codes of formulae are given in Table B.1.

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