
**Traditional Chinese medicine —
Coding rules for Chinese medicines in
supply chain management**

*Médecine traditionnelle chinoise — Règles de codage des médecines
chinoises dans la gestion de la chaîne logistique*

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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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Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

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.

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Introduction

The popularity of medicinal products derived from natural materials, particularly herbal materials, is increasing rapidly. For example, the international market for medicines used in traditional Chinese medicine (TCM) was valued at USD 16 billion and is increasing at a rate of 10 % to 20 % per year.

Most goods traded internationally use bar coding to monitor the movement and use of the products. For example, even pencils and erasers have bar codes which permit their individual identification. However, this does not currently apply to medicines used in TCM. While at least 70 countries now have administrative systems in place to regulate TCM, the lack of bar coding is a barrier to the increasing trade and to ensuring the identity and quality of ingredients and products for the well-being of communities.

This document introduces a bar coding for TCM which is consistent with existing standards. It also provides a basis for similar coding systems for the products of related traditional health systems.

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Traditional Chinese medicine — Coding rules for Chinese medicines in supply chain management

1 Scope

This document specifies coding rules for Chinese medicines to assist in supply chain management. The coding provides information such as the trade item, producing area, unit, grade, production date, batch number, quantity of medicines, and logistic unit. This includes Chinese Materia Medica and decoction pieces, but excludes granule forms of individual medicinals for prescriptions (GFIMP) and Chinese patent medicines (CPM).

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 15416, *Information technology — Automatic identification and data capture techniques — Bar code print quality test specification — Linear symbols*

ISO/IEC 15418, *Information technology — Automatic identification and data capture techniques — GS1 Application Identifiers and ASC MH10 Data Identifiers and maintenance*

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

ISO/IEC 15438, *Information technology — Automatic identification and data capture techniques — PDF417 bar code symbology specification*

ISO/IEC 16022, *Information technology — Automatic identification and data capture techniques — Data Matrix bar code symbology specification*

ISO/IEC 18000-6, *Information technology — Radio frequency identification for item management — Part 6: Parameters for air interface communications at 860 MHz to 960 MHz General*

ISO/IEC 18004, *Information technology — Automatic identification and data capture techniques — QR Code bar code symbology specification*

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 <http://www.iso.org/obp>
- IEC Electropedia: available at <http://www.electropedia.org/>

3.1

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

supply chain

linked set of resources and processes that begins with the sourcing of raw material and extends through the delivery of products or services to the end user across the modes of transport

Note 1 to entry: The supply chain may include vendors, manufacturing facilities, logistics providers, internal distribution centres, distributors, wholesalers and other entities that lead to the end user.

[SOURCE: ISO 28000:2007, 3.9]

3.3

supply chain management

management primarily concerned with the efficient integration of suppliers, factories, warehouses and stores so that the merchandise is produced and distributed in the right quantities, to the right locations and at the right time, and so as to minimize total system cost subject to satisfying service level requirements

3.4

global location number

GLN

GS1 identification key used to identify physical locations or parties

Note 1 to entry: The key comprises a GS1 Company Prefix, Location Reference, and Check Digit.

[SOURCE: GS1 General Specifications, modified]

3.5

application identifier

AI

numeric prefixes describing the meaning, structure, and function of the GS1 element strings so they can be correctly processed in users' application programs.

[SOURCE: GS1 General Specifications, modified]

3.6

serial shipping container code

SSCC

GS1 identification key used to identify logistics units

Note 1 to entry: The key comprises an Extension Digit, the GS1 Company Prefix, Serial Reference, and Check Digit.

[SOURCE: GS1 General Specifications, modified]

4 Coding principles

4.1 Uniqueness

Each kind of Chinese medicines corresponds to a unique code.

4.2 Compatibility

The coding rules are consistent with relevant existing International Standards.

4.3 Stability

The code for each Chinese medicine remains unchanged once assigned, as long as the basic characteristic of the medicinal does not change. Even if some Chinese medicines are discontinued for production and use, their codes should still be kept.

5 Information coding

5.1 Retail products of Chinese medicines code

As demonstrated in [Figure 1](#), coding of Chinese medicines adopts the structure of 13 digits of data. The structure given in ISO/IEC 15420 shall be applied.

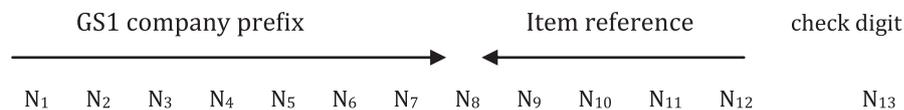


Figure 1 — Code structure

A GS1 company prefix is a unique string of 4 to 12 digits used to issue GS1 identification keys.

The first two or more digits of GS1 company prefix refer to GS1 prefix.

Item reference is usually formulated by manufacturers. When GS1 company prefix is composed of 8 digits of data, Item reference is composed of 4 digits of data. Otherwise, when GS1 company prefix is composed of 7 digits of data, item reference is composed of 5 digits of data.

The method calculation for check digit given in ISO/IEC 15420 shall be applied.

5.2 Medicinal code

A medicinal code is composed of 17 digits of data, which is closely related to the ISO 18668 series. The coding rules should be consistent with the requirements of ISO 18668-1 and the medicinal code should be consistent with ISO 18668-2, ISO 18668-3 and ISO 18668-4.

Coding data corresponding to application identifier (AI) “251” indicates reference to a source entity, here expressed by the date of the medicinal code.

See medicinal code in the ISO 18668 series.

5.3 Company internal information code

5.3.1 General principles

Company internal information, whose length is alterable, consists of alphanumeric characters, and refers to a permanent serial code distributed by the manufacturer to an entity.

Coding data corresponding to application identifier (AI) 91 indicates company internal information.

As demonstrated in [Table 1](#), the company internal information of Chinese medicines consists of 17 digits of data in 3 ranks, including producing area code, measurement unit code and grade code.

Table 1 — Code structure of company internal information

AI	Company internal information		
91	Producing area (GLN)	Measurement unit code	Grade code
	N ₁ N ₂ N ₃ N ₄ N ₅ N ₆ N ₇ N ₈ N ₉ N ₁₀ N ₁₁ N ₁₂ N ₁₃	N ₁₄ N ₁₅	N ₁₆ N ₁₇

5.3.2 Producing area code

The producing area code refers to the code of place where the crude material is produced. The producing area code adopts the rules of the global location number (GLN), it consists of 13 digits of data, and is

used to differentiate the same variety from different producing areas. As demonstrated in Table 2, the structure given in GS1 general specifications for GLN shall be applied.

Table 2 — Code structure of GLN

GS1 company prefix 	Location reference	Check digit
N ₁ N ₂ N ₃ N ₄ N ₅ N ₆ N ₇ N ₈ N ₉ N ₁₀ N ₁₁ N ₁₂		N ₁₃

5.3.3 Measurement unit code

Information of the measurement unit of Chinese medicines is used to distinguish different measurement units of the same variety. For example, cordyceps could be measured separately with measurement units such as kg, bag, and box. See Table 3 for details.

Table 3 — Measurement units code

Code	Measurement units
01	Gram
02	Kilogram
03	Millilitre
04	Bar
05	Piece
06	Bottle
07	Bag
08	Branch
09	Grain
10	Block
11	Pair
12	Box
13	Pound

5.3.4 Grade code

The grade code is used to identify different grades of Chinese medicines.

NOTE “00” indicates that this reserved coding is for future use on grading.

5.4 Code of production date

The production date is the production or assembly date determined by the manufacturer. The date may refer to the trade item itself or to items contained.

Coding data corresponding to application identifier (AI) “11” indicates the production date. See the code format in Table 4.

Table 4 — Code of production date

AI	Production Date		
11	Year	Month	Day
	N ₁ N ₂	N ₃ N ₄	N ₅ N ₆

NOTE 1 Year: it is denoted by two digits and cannot be omitted. For example, 2011 is denoted by “11”.

NOTE 2 Month: it is denoted by two digits and cannot be omitted. For example, January is denoted by “01”.

NOTE 3 Day: it is denoted by two digits. For example, the second day of a month is denoted by “02”. If a specific day is not necessary, it is replaced by “00”.

5.5 Code of batch number

Batch number indicates data information related to a trade account; it is applied for product tracing. Data information of batch numbers could be related to a trade account itself or its included items.

Coding data corresponding to application identifier (AI) “10” indicates the code of batch or lot number. See code format in [Table 5](#).

Table 5 — Code of batch number

AI	Name
10	X ₁ ...X _j (j ≤ 20)

5.6 Code of batch numbers in logistic unit

Coding data corresponding to application identifier (AI) “37” indicates the count of trade items contained in a logistic unit. See code format in [Table 6](#).

Table 6 — Code of batch number in logistic unit

AI	Number of trade account
37	X ₁ ...X _j (j ≤ 8)

Batch numbers: The logistic unit of batch numbers is represented by numeric character whose length is alterable and 8 is the maximum.

5.7 Code of logistic unit

The application identifier (AI) 00 indicates that the GS1 application identifier data field contains a serial shipping container code (SSCC). The SSCC is used to identify logistic units. See code format in [Table 7](#).

Table 7 — Code of logistic unit

Format of the element string			
AI	Serial shipping container code (SSCC)		
	Extension digit	GS1 company prefix	Serial reference
00	N ₁	N ₂ N ₃ N ₄ N ₅ N ₆ N ₇ N ₈ N ₉ N ₁₀ N ₁₁ N ₁₂ N ₁₃ N ₁₄ N ₁₅ N ₁₆ N ₁₇	Check digit N ₁₈

6 Representation of information identification

For automatic or artificial information collection of Chinese medicines, information identification in supply chains should be represented by carriers that must be kept or pasted on the external packing of medicinal products until they are consumed or damaged.

Data carriers of information identification in supply chain could be automatic identification carriers such as bar code, radio frequency label, etc.

6.1 One-dimensional bar code representation

6.1.1 One-dimensional bar code representation of retail trade account

When trade account of Chinese medicines is through point of sales (POS), one-dimensional bar code representation of EAN/UPC is recommended as demonstrated in [Figure 2](#). The technical requirements given in ISO/IEC 15420 shall be applied.



Figure 2 — One-dimensional bar code of retail trade account

6.1.2 One-dimensional bar code representation of non-retail trade account

When batches of Chinese medicines are not distributed through retail POS, one-dimensional bar code representation of GS1-128, ITF-14 or EAN/UPC is recommended.

When batches of Chinese medicines are not distributed through retail POS, one-dimensional bar code representation of GS1-128 combined with application identifiers (batch numbers, manufacturing date, production area, etc.) is recommended as demonstrated in [Figure 3](#). The technical requirements given in ISO/IEC 15416 shall be applied. Application identifiers given in ISO/IEC 15418 shall be applied.



Figure 3 — Code of non-retail trade account and its related one-dimensional bar code

6.1.3 One-dimensional bar code representation of logistic unit

One-dimensional bar code representation of GS1-128 as demonstrated in [Figure 4](#) is recommended to express logistic unit. The technical requirements given in ISO/IEC 15416 shall be applied. Application identifiers given in ISO/IEC 15418 shall be applied.



Figure 4 — One-dimensional bar code of logistic unit

6.2 Two-dimensional bar code representation

[Figure 5](#) shows the two-dimensional bar code representation of PDF417 bar code, [Figure 6](#) shows QR code and [Figure 7](#) shows data matrix. The technical requirements given in ISO/IEC 15438, ISO/IEC 18004 or ISO/IEC 16022 shall be applied.