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Traditional Chinese medicine — Coding system for Chinese medicines —

Part 1: Coding rules for Chinese medicines

Médecine traditionnelle chinoise — Système de codage des médecines chinoises —

Partie 1: Règles de codage des médecines chinoises

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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.

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The committee responsible for this document is ISO/TC 249, *Traditional Chinese medicine.*

ISO 18668 consists of the following parts, under the general title *Traditional Chinese medicine — Coding system for Chinese medicines*:

— *Part 1: Coding rules for Chinese medicines*

— *Part 2: Codes for decoction pieces*

— *Part 3: Codes for Chinese materia medica*

— *Part 4: Codes for granule forms of individual medicinals for prescriptions*

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Introduction

As the pharmaceutical materials extracted from natural and botanical products have become increasingly attractive, significant progress has been achieved in identifying new sources of natural products for traditional and alternative medicine. In particular, Chinese traditional medicine has been the focus of tremendous research, development and applications worldwide. Accordingly, Chinese medicinal materials are increasingly being used in countries around the world. Currently, there are more than 70 countries that have established administrative systems to regulate Chinese Medicine. 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 with great future potential. At the same time, concerns of harm to the body associated with the long-term use of synthetic drugs have been recognized. Therefore, many countries are developing vigorous controls and regulations on using antibiotics and other synthetic drugs, while recognizing the importance of traditional and alternative medicines. Thus, this brings more opportunities for the development of the market of Chinese medicines.

Today, bar codes are widely used for managing almost all ordinary products that are put up for sale, for example, an eraser or a pencil has its individually identifiable bar code. Yet so far, a bar coding system for products used in Chinese medicine has not been given sufficient attention, making it difficult to categorize the individual items for international trade and research development. This brings challenges and concerns in government supervision and proper use by patients. As products for medicinal use, Chinese medicines could have bar codes that can be integrated into the current bar code system that is used for other commercial products. In this way, bar codes can be used to track sources and monitor the quality of the products. Therefore, there is an urgent need to develop a bar code system for Chinese medicine products that will enable to identify each specific Chinese medicine product.

The Coding System of Chinese Medicines is developed based on science and research rooted in plant taxonomy, Chinese medicine, Chinese medicinal processing, and other established regulatory handbooks and guidelines of GS1 General standard, central product classification (CPC) and ISO/IEC 15420, etc. The codes help to translate complicated names of a wide variety of decoction pieces, Chinese Materia Medica (raw materials), and granule forms of individual medicinals for prescriptions into transparent digits. In this way, each Chinese medicine corresponds to a unique code as its identification.

The Coding System of Chinese Medicines aims to promote standardization and digitalization for Chinese medicine, to ensure authenticity, equality, fairness and transparency in international markets and trade and to facilitate government supervision and regulation of Chinese medicine. It is hoped that it will help pharmaceutical enterprises to manage workflow and increase economic returns. It will help healthcare delivery organizations, such as hospitals and dispensaries, to improve information management systems that can ensure the accuracy of dispensing, ensuring the safe and effective use of prescribed medicine.

As it has been previously acknowledged, Chinese decoction pieces are processed products of Chinese Materia Medica, which are also known as raw materials. Thus when designing the coding system for Chinese medicines, it is feasible that one set of rules could incorporate all the features of each category of Chinese medicines, as they share the same medicinal source and medical part. To be specific, their divergence and commodity attributes can be clearly described in one of the layers (layer 8) in this set of coding rules. Granule forms of individual medicinals for prescriptions are innovative products made from decoction pieces. Based on the same considerations of feasibility and cost-control, the granular forms can be included within the same set of rules for decoction pieces.

However, although Chinese patent medicines (CPM) are made from decoction pieces, their coding rules are more complicated and differ from decoction pieces. Therefore, this coding system is not fit for CPM, and coding rules for CPM need to be formulated separately.

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Traditional Chinese medicine — Coding system for Chinese medicines —

Part 1:
Coding rules for Chinese medicines

1 Scope

This part of ISO 18668-1 specifies rules to encode Chinese medicines, including decoction pieces, Chinese Materia Medica (raw materials) and granule forms of individual medicinals for prescriptions (GFIMP), but not Chinese patent medicines (CPM).

Relevant coding standards for Kampo medicine, Korean medicine and other traditional medicines will be separately formulated as needed by experts in these areas.

This part of ISO 18668-1 is suitable for decoction pieces, Chinese Materia Medica (raw materials), and granule forms of individual medicinals for prescriptions (GFIMP) in the fields of clinical medication, scientific research and teaching, and statistics and management.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. 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*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

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).

3.2
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.

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3.3
decoction piece
prescription medicinal processed from Chinese Materia Medica under the guidance of TCM and processing methods for Chinese medicines

Note 1 to entry: Decoction pieces are directly used in clinical practice or the production of prepared medicines.

3.4
granule form of individual medicinal for prescriptions
GFIMP
granular preparation processed from single decoction piece after extraction, concentration, and drying

Note 1 to entry: This refers to a preparation of decoction pieces that can be directly dispensed without decocting.

3.5
layer
set of the characters within the code

EXAMPLE A sub-field within the code.

4 Coding principles

4.1 Uniqueness

Each variety and processed form corresponds to a unique code.

4.2 Scientific integrity

The most stable properties, attributes, or characteristics of each Chinese medicine are selected as basis for classification and coding. The basic attributes, the main applications, as well as its quality, of each Chinese medicine are reflected in the codes.

4.3 Scalability

The coding rules allow sufficient space for expansion.

4.4 Compatibility

The coding rules are consistent with relevant existing International Standards.

4.5 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 Coding technology

5.1 Technical basis

5.1.1 Layer 1

Layer 1 with 1 digit, Chinese medicines, with the categories of agriculture, forestry, animal husbandry, and fishery are symbolized by 0, which is developed according to central product classification (CPC) developed by United Nations Statistical Commission.

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