INTERNATIONAL STANDARD

ISO 18668-4

First edition
2017-03

Traditional Chinese medicine — Coding system for Chinese medicines —

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

Médecine traditionnelle chinoise — Système de codage des médecines chinoises —

Partie 4: Codes pour les granulés de médicaments individuels pour les prescriptions

Reference number
ISO 18668-4:2017(E)

ISO copyright office
Ch. de Blandonnet 8 • CP 401
CH-1214 Vernier, Geneva, Switzerland
Tel. +41 22 749 01 11
Fax +41 22 749 09 47
copyright@iso.org
www.iso.org

Contents

Page

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).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

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.

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

A list of all parts in the ISO 18668 series can be found on the ISO website.

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 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 for 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 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 for 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, improve information management systems that can ensure the accuracy of dispensing, ensuring the safe and effective use of prescribed medicine.

Chinese medicines are substances or combinations of substances used under the guidance of traditional Chinese medicine (TCM) theory for medical care and the prevention and treatment of disease, including Chinese Materia Medica, decoction pieces, granule forms of individual medicinals for prescriptions (GFIMP), and Chinese patent medicines (CPM). 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.

Traditional Chinese medicine — Coding system for Chinese medicines —

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

1 Scope

This document encodes 777 kinds of granule forms of individual medicinals for prescriptions, according to the rules in ISO 18668-1.

This document is suitable for coding of granule forms of individual medicinals for prescriptions, as well as granule forms of individual medicinals for prescriptions in the fields of clinical medication, scientific research, teaching, statistics and management.

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 18668-1, *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 terms and definitions in ISO 18668-1 apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

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

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

4 Coding principles

4.1 Uniqueness

Each variety and processed form corresponds to a unique code.

4.2 Scientificity

By applying scientific research to decide the classification methods and principles, the most stable properties, attributes, and characteristics of each Chinese medicine are used as basis for classification and coding. Thus, the structure of 17 digits with 10 layers as coding rules for Chinese medicines covers the information on medicinal source, medicinal part, specification, and processing method, which respectively represent the basic characteristics, commercial attributes, and professional attributes of Chinese medicines.