



BSI Standards Publication

**Health informatics — Categorical
structure for Chinese materia medica
products manufacturing process**

National foreword

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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 of 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 www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 215, *Health informatics*.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

Chinese materia medica is widely utilized as a part of complementary and alternative medicine throughout East Asia and western countries. In order to ensure the quality and therapeutic effect of Chinese medicines, it is important to use a proper manufacturing process of Chinese materia medica.

The manufacturing process of traditional Chinese materia medica products is a complicated control system engineering including equipment, technology and quality. The manufacturing process proposed in this document is a part of traditional Chinese materia medica control system engineering.

There are many types of manufacturing process, but systematic terminology definitions and semantic links did not exist, which often caused difficulties for production management and metadata analysis.

This arises from two reasons: firstly, a wide variety of dosage forms and manufacturing process are difficult to classify accurately; secondly, the categorial structure of processing Chinese materia medica has not been published.

This document provides a categorial structure which could solve these problems and improve the scientific level of production management of Chinese medicines.

Health informatics — Categorial structure for Chinese materia medica products manufacturing process

1 Scope

This document specifies the whole manufacturing process of Chinese materia medica products by defining a set of domain constraints of sanctioned characteristics, each composed of a relationship and an applicable categorial structure. It includes three process categories: processing, extracting and preparation.

This document is not applicable to Japanese traditional KAMPO medicinal products.

2 Normative references

There are no normative references in this document.

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 General

3.1.1 concept

unit of knowledge created by a unique combination of *characteristics* (3.1.4)

Note 1 to entry: A concept can have one or more names. It can be represented using one or more terms, pictures, icons or sounds.

3.1.2 category

division of sets of entities regarded as having particular shared *characteristics* (3.1.4)

EXAMPLE Freeze drying, spray drying and all other drying share characteristics particular to the category drying.

Note 1 to entry: Categories can be more or less general. Where one category is subsumed by another, there is a relation asserted to obtain a hierarchy between the more specific or subsumed category and the more general or subsuming category. For example, parenteral route is more general than intravenous route.

3.1.3 categorial structure

minimal set of domain constraints for representing concept systems in a subject field

3.1.4 characteristic

abstraction of a property, of an object or of a set of objects

EXAMPLE Fever is a characteristic symptom of flu.