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Traditional Chinese medicine — Requirements for process traceability systems in Chinese materia medica and decoction pieces —

Part 1: Components

Médecine traditionnelle chinoise — Exigences relatives au système de traçabilité du processus pour la Materia Medica chinoise et les décoctions —

Partie 1: Composants

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Foreword

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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 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 249, *Traditional Chinese medicine*.

A list of all parts in the ISO 23963 series can be found on the ISO website.

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 medicine (medicinal plants, animals and minerals) originates from a wide variety of different sources of supply. The production documentation is handled differently by each company and important manufacturing steps are usually not fully documented. Several companies are usually involved in the manufacturing process of Chinese medicine and relevant information is often not passed on fully from one company to the other. This makes it very difficult for manufacturers and consumers to retrace the entire production process (e.g. cultivation, harvesting, processing, storage and logistics) and to assess the quality and safety of Chinese medicine. The lack of transparency in the manufacturing process slows down to a certain extent the further development and internationalization of traditional Chinese medicine. Therefore, a supply chain traceability system is needed which ensures that the documentation of all product-relevant information is standardized and available at all times. Such a system will enable companies to better evaluate their suppliers and to convince end users of the quality and safety of their products.

This document is consistent with ISO 18668-1, ISO 18668-2, ISO 18668-3 and ISO 20333. It includes the application of these documents and provides a solution to improve the management of all processes related to Chinese medicine, contributes to the establishment of the traditional Chinese medicine supply chain traceability system and quality-investigating mechanism, enhances product quality and competitiveness, protects consumers' rights and ensures safe and effective application in clinical use.

This document can promote the process of standardization, informatization and modernization for traditional Chinese medicine.

Traditional Chinese medicine — Requirements for process traceability systems in Chinese materia medica and decoction pieces —

Part 1: Components

1 Scope

This document specifies the requirements for process traceability systems in Chinese materia medica and decoction pieces, including checkpoints of traceability information about the planting or breeding and circulation of Chinese materia medica, and the manufacturing, processing and use of entities of decoction pieces.

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 22217, *Traditional Chinese medicine —Storage requirements for raw materials and decoction pieces*

3 Terms and definitions

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

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

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

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

3.1
traceability
ability to track Chinese materia medica and decoction pieces forward through specified stages of planting or breeding, manufacturing, processing, circulation, transport, storage and usage

3.2
traceability system
manual or electronic system that provides the ability to access any or all information relating to the material or product under consideration throughout their life cycle, by means of accessing documented information

3.3
Chinese materia medica
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.

[SOURCE: ISO 18668-1:2016, 3.2, modified — abbreviated term CMM removed.]