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

lecin, matière Médecine traditionnelle chinoise — Exigences de conservation pour





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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).

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

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

Raw materials (Chinese materia medica) and decoction pieces have originated from various and complex sources, such as plants, animals and minerals. Also, different raw materials and decoction pieces contain different compositions. Without the proper storage conditions (regarding temperature, humidity, air and sunlight), quality variation could easily occur. There are many possible variations in the quality of raw materials and decoction pieces, including damage by worms or vermin, mould, oil extravasation, dicolouring, loss of odour, efflorescence, deliquescence, adhesion, volatilization and decay. In other words, inappropriate storage conditions and methods could lead to quality variation and economic loss, as well as variation in the efficacy and safety of raw materials and decoction pieces in clinical medication use.

Storage requirements for raw materials and decoction pieces give scientific, reasonable, economic and effective storage conditions for different raw materials and decoction pieces. In these conditions, raw materials and decoction pieces can be effectively protected from quality variation and the safety, quality and clinical effectiveness of raw materials and decoction pieces can thus be guaranteed.

This document gives information that can remind the user to give priority to the unstable or expensive raw materials and decoction pieces; to avoid predictable quality variation; and to reduce losses. For example, raw materials and decoction pieces rich in grease, starch and protein could be damaged by worms; raw materials and decoction pieces rich in grease, volatile oil and mucilage could have oil extravasation at high temperatures and relative humidity; or raw materials and decoction pieces rich in volatile oil could lose their odour.

As national implementation may differ, national standards bodies are invited to modify the values given in 5.2.1, 5.2.2, 5.2.3 and 5.2.4 in their national standards. Examples of national and regional values are given in $\frac{Annex A}{A}$.

Examples of storage attention for raw materials and decoction pieces to avoid quality variations are given in $\underbrace{Annex\ B}$. Information of a traditional Chinese medicine storage method named "Collaborative storage" is given in $\underbrace{Annex\ C}$. Examples of toxic and rare raw materials and decoction pieces needing close monitoring are given in $\underbrace{Annex\ D}$.

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

1 Scope

This document specifies the general storage requirements for raw materials and decoction pieces.

It is applicable to the storage of raw materials and decoction pieces used in traditional Chinese medicine.

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

storage

preservation measures for keeping raw materials and decoction pieces under defined conditions, retaining effective ingredients and biological activity of raw materials and decoction pieces, preventing spoilage, quality variation and contamination, and ensuring quality and safety of raw materials and decoction pieces

3.2

raw materials

Chinese materia medica

CMM

medicinal parts of medicinal plants, animals and minerals after preliminary processing, which are used as crude materials to make decoction pieces in Chinese medicine

[SOURCE: ISO 18662-1:2017, 3.1, modified — Note 1 to entry removed.]

3.3

decoction piece

prescription medicinal processed from Chinese materia medica under the guidance of TCM theory and processing methods for Chinese medicines

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

[SOURCE: ISO 18668-1:2016, 3.3]

3.4

protected from light

kept in a container that can prevent transmittance of light affecting the specified properties and quality of the contents under ordinary conditions of handling, shipment and storage