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Traditional Chinese medicine — Fermented *Cordyceps* powder

Médecine traditionnelle chinoise — Poudre de Cordyceps *fermenté*

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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*.

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

Cordyceps sinensis, known as “冬虫夏草”, Chinese Pinyin *Dong Chong Xia Cao* (winter worm, summer plant), is a rare raw material used in traditional Chinese medicine. *Cordyceps sinensis* enjoys equal popularity with ginseng and velvet and ranks first among these three tonic medicines. The use of *Cordyceps sinensis* can be traced to AD 863, during the Tang Dynasty, in the Youyang Essays by Duan Chengshi. In recent years, the efficacy of *Cordyceps sinensis* has been further confirmed and its extensive and significant efficacy is acknowledged worldwide.

The bioactivities of *Cordyceps sinensis* include immunoregulation, anti-bacteria, anti-cancer, anti-oxidation, anti-aging, blood sugar control and fat reduction. Due to the specific environment required for the growth of *Cordyceps sinensis*, the resources of wild *Cordyceps sinensis* are limited. Increasing market demand has therefore resulted in high prices. Driven by increased interest, wild *Cordyceps sinensis* is facing extinction due to plunder digging, which impacts its natural ecological environment. The culture of *Cordyceps sinensis* has become a hot topic of research, with a focus on liquid fermentation technology. Fermented *Cordyceps* powder is manufactured with strain extracted from wild *Cordyceps sinensis* by low-temperature liquid fermentation, simulating the growth environment of wild *Cordyceps sinensis.* Quality control for fermented *Cordyceps* powder is complicated. There are many functional active substances in fermented *Cordyceps* powder, including polysaccharide compounds, alkaloids (Cordycepin), peptide compounds, sterols, terpenoids and other secondary metabolites. The content of these substances in fermented *Cordyceps sinensis* determines to a large extent the quality and efficacy of fermented *Cordyceps powder*. Traditional analytical methods vary and depend highly on experience. It is difficult to determine the quality of fermented *Cordyceps* powder with existing methods.

A guarantee of the quality of fermented *Cordyceps* powder is crucial to ensure the quality and safety of medicines and health products made from fermented *Cordyceps* powder. Exploring quality control methods of fermented *Cordyceps* powder and creating a standard combining traditional Chinese medicine characteristics and current technology will have profound influence on the industry of fermented *Cordyceps* powder.

As national implementation can differ, national standards bodies are invited to modify the values given in 4.5, 4.8 and 4.9. Reference values of national and regional limits of heavy metals, microbiological examination and aflatoxins are given in Annex E.

Traditional Chinese medicine — Fermented *Cordyceps* powder

1 Scope

This document specifies a set of requirements and a test method to control the quality of fermented *Cordyceps* powder, including test items such as identification, assay, water content, residue on ignition, microbial limit and heavy metals.

It is applicable to fermented *Cordyceps* powder which is produced by liquid fermentation with extracted strain of *Ophiocordyceps sinensis* (Berk.).

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 1762, *Paper, board, pulps and cellulose nanomaterials — Determination of residue (ash content) on ignition at 525 °C*

ISO 6673, *Green coffee — Determination of loss in mass at 105 degrees C*

ISO 13903:2005, *Animal feeding stuffs — Determination of amino acids content*

ISO 18664, *Traditional Chinese Medicine — Determination of heavy metals in herbal medicines used in Traditional Chinese Medicine*

ISO 22283, *Traditional Chinese medicine — Determination of aflatoxins in natural products by LC-FLD*

ISO 22467, *Traditional Chinese medicine — Determination of microorganisms in natural products*

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
***Ophiocordyceps sinensis* (Berk.)**
sac fungi parasite in bat moth larvae

3.2
fermented *Cordyceps* powder
dried powder of mycelium obtained by liquid fermentation of *Ophiocordyceps sinensis* (Berk.)