INTERNATIONAL STANDARD

ISO 22467

First edition
2021-10

Traditional Chinese medicine — Determination of microorganisms in natural products

Médecine traditionnelle chinoise — Détermination des micro-organismes dans les produits naturels

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Reference number
ISO 22467:2021(E)

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Published in Switzerland

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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 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.

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Introduction

Natural products used in traditional Chinese medicine are widely used around the world due to their high medicinal values and mild side effects. It is a common phenomenon that natural products are contaminated by microorganisms which not only impact their quality and efficacy, but also restrict the international trade in them and related products. Although the Pharmacopeia of the People's Republic of China, the British Pharmacopoeia, the Japanese Pharmacopoeia, the European Pharmacopoeia and the United States Pharmacopeia have stipulated the microbial limits of natural products, there is no International Standard for microorganism detection methods, which adversely affects communication and trade between researchers and factories in different countries. Furthermore, microorganism levels on or in natural products usually exceed the maximum limit levels set by many international organizations and countries due to the lack of an International Standard.

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Traditional Chinese medicine — Determination of microorganisms in natural products

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1 Scope

This document specifies test methods to determine microorganisms in natural products. It is applicable only to natural products used in traditional Chinese medicine, including raw materials, herbal pieces and preparations.

2 Normative reference

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
sterility
state of being free from viable microorganisms

Note 1 to entry: In practice, no such absolute statement regarding the absence of microorganisms can be proven.

[SOURCE: ISO 11139:2018, 3.274]

3.2
microbial enumeration test
quantitative counting of mesophilic bacteria and fungi which may grow under aerobic conditions

4 Symbols and abbreviated terms

ATCC	American Type Culture Collection
CMCC	National Center for Medical Culture Collections
CIP	Collection de Bactéries de I'Institut Pasteur
IMI	International Mycological Institute
IP	Institut Pasteur
MPN	most-probable-number
NBRC	Biological Resource Center, National Institute of Technology and Evaluation
NCIMB	National Collection of Industrial and Marine Bacteria Ltd

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