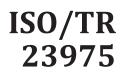
TECHNICAL REPORT



First edition 2019-11

Priority list of single herbal medicines



Reference number ISO/TR 23975:2019(E)



© ISO 2019

All rights reserved. Unless otherwise specified, or required in the context of its implementation, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office CP 401 • Ch. de Blandonnet 8 CH-1214 Vernier, Geneva Phone: +41 22 749 01 11 Fax: +41 22 749 09 47 Email: copyright@iso.org Website: www.iso.org

Published in Switzerland

Page

Contents

Forew	rord	iv
Introd	luction	v
1	Scope	1
2	Normative references	1
3	Terms and definitions	1
4	Principles	1
5	Technical indexes5.1International trading5.2Single herbal medicines recorded in pharmacopoeias5.3Safety concerns5.4Single herbal medicine standards published or under development5.5Endangered species	1 3 36 43
6	Data processing 6.1 Expert consultation 6.2 Data statistics	44 44 44
7	Single herbal medicines in order of priority	
Annex	A (informative) Priority list of single herbal medicines ranked from 101 to 366	
Biblio	graphy	

ISO/TR 23975:2019(E)

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).

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 <u>www.iso.org/members.html</u>.

Introduction

Being a significant part of traditional medicine systems and general health services, traditional Chinese medicine is estimated to be used in over 180 countries and regions around the world. This is reflected by the statistics cited from the WHO report that there are 4 billion people in the world using herbal medicines, accounting for 80 % of the total world population. Asia, North America, and Europe are regarded as the major markets for herbal medicines. Moreover, incomplete Chinese customs statistics show that the import and export of herbal medicine products in China was worth over 4,7 billion USD in 2015. Therefore, it is very important to develop globally harmonized standards in order to ensure the safety of consumers. In particular, those herbal medicines which have been reported to cause adverse drug reactions (ADR) are drawing much attention from national health administrations.

There are a great number of single herbs on the market; for instance, 618 kinds of herbs have been included in the Pharmacopoeia of the People's Republic of China. Currently, organizations, regions and countries including ISO, WHO, the European Union, China, Japan, Korea, the USA, the UK and Thailand are making valuable contributions by developing standards for single herbs. This document presents a list of single herbal medicines in order of priority for the purposes of developing standards on single herbs in a scientific and orderly manner. This document can be used as a reference by any organization wishing to develop standards on single herbal medicines.

The following factors have been considered in setting the priorities:

- the trade volume of each single herbal medicine in the global market;
- whether the herbal medicine is recorded by the Pharmacopoeia of the People's Republic of China, Hong Kong Chinese Materia Medica Standards, the Japanese Pharmacopoeia, the Korean Pharmacopoeia, the European Pharmacopoeia, the United States Pharmacopoeia or the Thai Herbal Pharmacopoeia;
- whether there are potential risks from its use;
- whether the herbal medicine is listed in the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES)^[27];
- opinions from experts.

this document is a preview demendence of the document is a preview demendence of the document of the document

Traditional Chinese medicine — Priority list of single herbal medicines for developing standards

1 Scope

This document provides a reference of single herbal medicines in order of their priority in the development of international standards.

2 Normative references

There are no normative references in this document.

3 Terms and definitions

No terms and definitions are listed in this document.

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/

4 Principles

4.1 Herbal medicines which have a large international trading value are listed as high priority.

4.2 Standards of common herbal medicines recorded in the *Pharmacopoeia of the People's Republic of China, Hong Kong Chinese Materia Medica Standards,* the *Japanese Pharmacopoeia,* the *Korean Pharmacopoeia,* the *European Pharmacopoeia,* the *United States Pharmacopoeia* and the *Thai Herbal Pharmacopoeia* are listed as high priority.

4.3 Herbal medicines that have safety concerns, such as those widely reported to cause ADR, are listed as high priority.

4.4 Single herbal medicines for which there are existing ISO standards are listed as high priority.

4.5 Herbal medicines which are included in CITES are listed as low priority.

5 Technical indexes

5.1 International trading

<u>Table 1</u> provides information on single herbal medicines which had a large international trading value in China from 2012 to 2016 (sorted by export value).