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

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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

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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

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.

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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

[Table 1](#) provides information on single herbal medicines which had a large international trading value in China from 2012 to 2016 (sorted by export value).