
**Traditional Chinese medicine —
Guidelines and specification for
Chinese materia medica**

*Médecine traditionnelle chinoise — Lignes directrices et spécification
relatives aux matières médicinales chinoises*

STANDARDSISO.COM : Click to view the full PDF of ISO 21300:2019



STANDARDSISO.COM : Click to view the full PDF of ISO 21300:2019



COPYRIGHT PROTECTED DOCUMENT

© 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

Contents

	Page
Foreword	iv
Introduction	v
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
4 Requirements	2
4.1 Total ash	2
4.2 Sulfated ash	2
4.3 Ash insoluble in hydrochloric acid	2
4.4 Heavy metals	2
4.5 Foreign matter	2
4.6 Identification	2
4.7 Pesticide residues	2
4.8 Sulfur dioxide	2
4.9 Aflatoxin	3
5 Indicators of the specification	3
5.1 Origin	3
5.2 Growing method	3
5.3 Medicinal parts	4
5.4 Harvest time	4
5.5 Primary processing	4
5.6 Extraneous matter rate	5
5.7 Morphology	5
5.7.1 Individual number per 500 g	5
5.7.2 Length per piece	6
5.7.3 Thickness per piece	6
5.7.4 Diameter per piece	7
5.7.5 Colour	7
6 Marking, labelling, packaging, transport and storage	8
6.1 Marking and labelling	8
6.2 Packaging	8
6.3 Transport and storage	8
Bibliography	9

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 www.iso.org/members.html.

Introduction

Chinese materia medica is a special commodity used for preventing and treating diseases. Chinese materia medica is imported and exported by many countries, with important differences in quality.

This document is intended to provide a basis for fixing the price of different Chinese materia medica. It is intended to help regulate manufacturing and distribution, maintain quality, safety and market orders, and promote the development of trade and exchange in Chinese materia medica.

STANDARDSISO.COM : Click to view the full PDF of ISO 21300:2019

STANDARDSISO.COM : Click to view the full PDF of ISO 21300:2019

Traditional Chinese medicine — Guidelines and specification for Chinese materia medica

1 Scope

This document specifies the general requirements for Chinese materia medica specification. This specification is relevant for dividing Chinese materia medica into categories. It provides guidelines for writing the specifications of individual Chinese materia medica.

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 21371, *Traditional Chinese medicine — Labelling requirements of products intended for oral or topical use*

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

Chinese materia medica

CMM

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

Note 1 to entry: The different nomenclatures of the Chinese materia medica in use are described as follows:

- Latin name: Latin pharmaceutical name of the Chinese materia medica. In the Latin name, the genus name or genus name plus species name is followed by the applicable medicinal parts. Items are listed in alphabetical order of the Latin name for easy and convenient searching.
- Chinese name: Han (Chinese) character name of the Chinese materia medica. Han characters include both the simplified character and the traditional character, which is given in parentheses.
- Pinyin name: Pinyin name (Chinese phonetic) of the Chinese materia medica. The “four tones” have been added in Pinyin to facilitate practice by users. Pinyin syllabication (in parentheses) is provided to facilitate correct pronunciation.
- Scientific name: Latin scientific name of the source of the Chinese materia medica.
- English name: Commonly used English name of the Chinese materia medica.

[SOURCE: ISO 18662-1:2017, 3.1]

3.2

specification

explicit set of requirements to be satisfied for Chinese materia medica

3.3

category

collection of Chinese materia medica of the same species which has common features

3.4

primary processing

stage of the pre-treatment of natural materials during the collecting and harvesting process by which the raw materials are transformed into medicinal materials

3.5

extraneous matter rate

rate of the matter of a given plant which is not retained for use as Chinese materia medica

3.6

origin

biological species of Chinese materia medica

4 Requirements

4.1 Total ash

The mass fraction of total ash of the Chinese materia medica shall be determined.

4.2 Sulfated ash

The mass fraction of sulfated ash of the Chinese materia medica shall be determined depending on the characteristics of the Chinese materia medica.

4.3 Ash insoluble in hydrochloric acid

The mass fraction of ash insoluble in hydrochloric acid of the Chinese materia medica shall be determined depending on the characteristics of the Chinese materia medica.

4.4 Heavy metals

The contents of heavy metals shall be determined depending on the characteristics of the Chinese materia medica.

4.5 Foreign matter

The contents of foreign matter shall be determined.

4.6 Identification

The contents of the marker compounds shall be identified.

4.7 Pesticide residues

The contents of pesticide residues shall be determined depending on the characteristics of the Chinese materia medica.

4.8 Sulfur dioxide

The contents of sulfur dioxide shall be determined depending on the characteristics of the Chinese materia medica.

4.9 Aflatoxin

The contents of aflatoxin shall be determined depending on the characteristics of the Chinese materia medica.

5 Indicators of the specification

5.1 Origin

Different origins for the same Chinese materia medica, which may result in differences in appearance, should be indicated in order to distinguish between the different categories.

EXAMPLE The categories of *Curcumae Radix* can be determined by different origins. The colour of the cross section of the *Curcumae Radix* originating from Guiyujin [see [Figure 1 a\)](#)] is lighter than the one originating from Huangsi Yujin [see [Figure 1 b\)](#)].



a) *Curcumae Radix*
(Origin: Guiyujin)



b) *Curcumae Radix*
(Origin: Huangsi Yujin)

Figure 1 — Different categories of *Curcumae Radix*

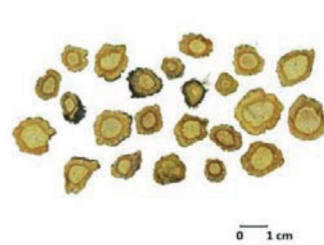
5.2 Growing method

Different growing methods (cultivated and wild) for the same Chinese materia medica, which may result in differences in appearance, should be indicated in order to distinguish between the different categories.

EXAMPLE The categories of *Saposhnikoviae Radix* can be determined by different growing methods. The wild *Saposhnikoviae Radix* [see [Figure 2 a\)](#)] is lighter and has a shallow pattern on the cross section. Cultivated *Saposhnikoviae Radix* [see [Figure 2 b\)](#)] is heavier and has a clear pattern on the cross section.



a) *Saposhnikoviae Radix*
(Wild)



b) *Saposhnikoviae Radix*
(Cultivated)

Figure 2 — Different categories of *Saposhnikoviae Radix*

5.3 Medicinal parts

Different medicinal parts for the same Chinese materia medica, which may result in differences in appearance, should be indicated in order to distinguish between the different categories.

EXAMPLE The categories of *Notoginseng Radix et Rhizoma* can be determined by different medicinal parts. The main root is stout and thick [see [Figure 3 a\)](#)], whereas the branching root is small and thin [see [Figure 3 b\)](#)].

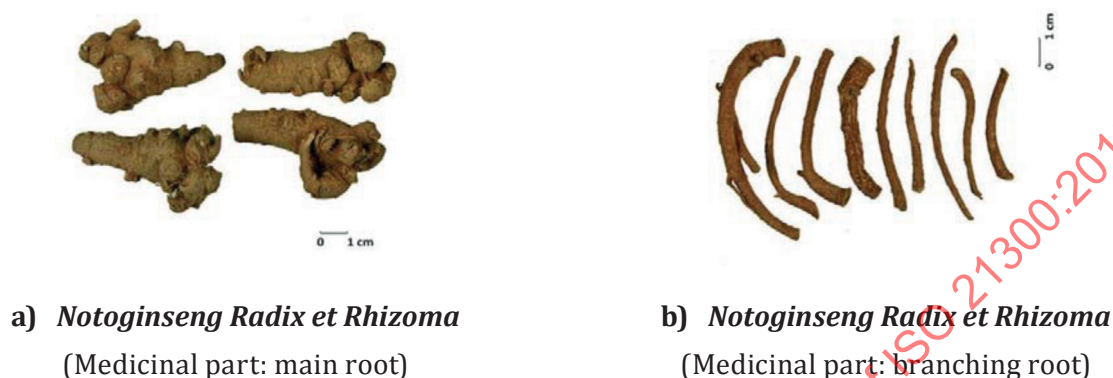


Figure 3 — Different categories of *Notoginseng Radix et Rhizoma*

5.4 Harvest time

Different harvest periods for the same Chinese materia medica, which may result in differences in appearance, should be indicated in order to distinguish between the different categories.

EXAMPLE The categories of *Forsythiae Fructus* can be determined by different harvest periods. *Forsythiae Fructus* harvested in autumn is dark green without cracks [see [Figure 4 a\)](#)]; *Forsythiae Fructus* harvested in winter is brownish yellow with cracks [see [Figure 4 b\)](#)].



Figure 4 — Different categories of *Forsythiae Fructus*

5.5 Primary processing

Different primary processing methods for the same Chinese materia medica, which may result in differences in appearance, should be indicated in order to distinguish between the different categories.

EXAMPLE The categories of *Dioscoreae Rhizoma* can be determined by different primary processing methods. *Dioscoreae Rhizoma* [see [Figure 5 a\)](#)] only undergoes peeling and drying operations during harvest season. *Dioscoreae Rhizoma* [see [Figure 5 b\)](#)] needs peeling, kneading, polishing and drying. However, there is no difference in their curative effects.

a) *Dioscoreae Rhizoma*

(Primary processing: peeling and drying)

b) *Dioscoreae Rhizoma*

(Primary processing: peeling, kneading, polishing and drying)

Figure 5 — Different categories of *Dioscoreae Rhizoma*

5.6 Extraneous matter rate

Different extraneous matter rates for the same Chinese materia medica, which may result in differences in appearance, should be indicated in order to distinguish between the different categories.

EXAMPLE The categories of *Lonicerae Japonicae Flos* can be determined by different extraneous matter rates. The medicinal part of *Lonicerae Japonicae Flos* is the flower bud. The flower buds are harvested with leaves and stems, which are not medicinal parts. As a result, flower buds can be divided into various categories according to the amount of leaves and stems that they contain. In [Figure 6 a\)](#), the extraneous matter rate of *Lonicerae Japonicae Flos* is low. In [Figure 6 b\)](#), the extraneous matter rate of *Lonicerae Japonicae Flos* is high.

a) *Lonicerae Japonicae Flos*

(Extraneous matter rate: low)

b) *Lonicerae Japonicae Flos*

(Extraneous matter rate: high)

Figure 6 — Different categories of *Lonicerae Japonicae Flos*

5.7 Morphology

5.7.1 Individual number per 500 g

Different individual numbers per 500 g for the same Chinese materia medica, which may result in differences in appearance, should be indicated in order to distinguish between the different categories.

EXAMPLE The categories of *Rehmanniae Radix* can be determined by different individual numbers per 500 grams. In [Figure 7 a\)](#), the individual number per 500 grams is less than the individual number per 500 grams in [Figure 7 b\)](#).

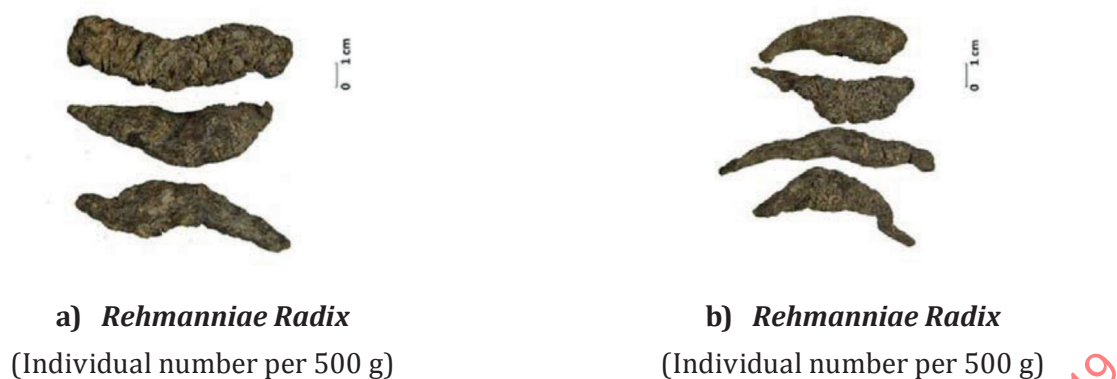


Figure 7 — Different categories of *Rehmanniae Radix*

5.7.2 Length per piece

Different lengths per piece for the same Chinese materia medica, which may result in differences in appearance, should be indicated in order to distinguish between the different categories.

EXAMPLE *Asparagi Radix* can be divided into several categories based on length. [Figure 8 a\)](#) is long and [Figure 8 b\)](#) is short.



Figure 8 — Different categories of *Asparagi Radix*

5.7.3 Thickness per piece

Different thicknesses per piece for the same Chinese materia medica, which may result in differences in appearance, should be indicated in order to distinguish between the different categories.

EXAMPLE The categories of *Magnoliae Officinalis Cortex* can be determined by different thickness. The thicker ones have been growing for a long time [see [Figure 9 b\)](#)] and vice versa [see [Figure 9 a\)](#)].