



International
Standard

ISO 9109

**Traditional Chinese medicine —
Rehmannia glutinosa root**

*Médecine traditionnelle chinoise — Racine de Rehmannia
glutinosa*

**First edition
2024-01**

iTeh Standards
(<https://standards.iteh.ai>)
Document Preview

ISO 9109:2024

<https://standards.iteh.ai/catalog/standards/iso/2c989d3f-f7b6-4d13-986a-009e0d1fd7c6/iso-9109-2024>

iTeh Standards
(<https://standards.iteh.ai>)
Document Preview

ISO 9109:2024

<https://standards.iteh.ai/catalog/standards/iso/2c989d3f-f7b6-4d13-986a-009e0d1fd7c6/iso-9109-2024>



COPYRIGHT PROTECTED DOCUMENT

© ISO 2024

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
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 Description	2
5 Requirements	2
5.1 General characteristics	2
5.2 Morphological characteristics	3
5.3 Microscopic characteristics	3
5.4 Moisture	3
5.5 Total ash	3
5.6 Acid-insoluble ash	4
5.7 Water-soluble extractives	4
5.8 Thin-layer chromatogram (TLC) identification	4
5.9 Content of marker compounds	4
5.10 Heavy metals	4
5.11 Pesticide residues	4
5.12 Sulfur dioxide residues	4
5.13 Grading	4
6 Sampling	4
7 Test methods	4
7.1 Macroscopic identification	4
7.2 Determination of moisture	4
7.3 Determination of total ash	4
7.4 Determination of acid-insoluble ash	5
7.5 Determination of water-soluble extractives	5
7.6 Thin-layer chromatogram (TLC) identification	5
7.7 Determination of marker compounds	5
7.8 Determination of heavy metals	5
7.9 Determination of pesticide residues	5
7.10 Determination of sulfur dioxideresidues	5
8 Test report	5
9 Packaging, storage and transportation	5
10 Marking and labelling	6
Annex A (informative) Identification of catalpol	7
Annex B (informative) Identification of verbascoside	9
Annex C (informative) Determination of catalpol content	11
Annex D (informative) Determination of rehmannioside D content	14
Annex E (informative) Example of traditional grading of <i>Rehmannia glutinosa</i> root	17
Annex F (informative) National and regional requirements for <i>Rehmannia glutinosa</i> root	18
Bibliography	20

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).

ISO draws attention to the possibility that the implementation of this document may involve the use of (a) patent(s). ISO takes no position concerning the evidence, validity or applicability of any claimed patent rights in respect thereof. As of the date of publication of this document, ISO had not received notice of (a) patent(s) which may be required to implement this document. However, implementers are cautioned that this may not represent the latest information, which may be obtained from the patent database available at www.iso.org/patents. ISO shall not be held responsible for identifying any or all such patent rights.

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.

ISO 9109:2024

<https://standards.iteh.ai/catalog/standards/iso/2c989d3f-f7b6-4d13-986a-009e0d1fd7c6/iso-9109-2024>

Introduction

Rehmannia glutinosa root, dried root of *Rehmannia glutinosa* Libosch. (Fam. Scrophulariaceae), is one of the most commonly used herbs in traditional Chinese medicine. It has a long history of use in East and Southeast Asian countries for relieving heat and cooling the blood, and for nourishing yin and body fluid, meaning promoting overall health and body fluid circulation.

Clinically, *Rehmannia glutinosa* root is used for the prevention and treatment of diabetes, inflammation, cancer and other diseases. At present, *Rehmannia glutinosa* root and its processed products occupy a huge share of the international market. The international trading amount of *Rehmannia glutinosa* root ranks in the top ten of Chinese materia medica in countries including China, the Republic of Korea, Japan, Viet Nam and Malaysia. However, many problems can affect the quality of *Rehmannia glutinosa* root, such as different quality requirements among different countries and regions, different preparation methods, and different packaging, transportation and storage conditions. Therefore, the establishment of an International Standard is necessary to meet the quality requirements of *Rehmannia glutinosa* root, supporting its clinical effectiveness and safety.

As national implementation can differ, national standards bodies are invited to modify the values given in [5.4](#), [5.5](#) and [5.6](#) in their national standards. Examples of national and regional values are given in [Annex F](#).

iTeh Standards
(<https://standards.iteh.ai>)
Document Preview

[ISO 9109:2024](#)

<https://standards.iteh.ai/catalog/standards/iso/2c989d3f-f7b6-4d13-986a-009e0d1fd7c6/iso-9109-2024>

Traditional Chinese medicine — *Rehmannia glutinosa* root

1 Scope

This document specifies the requirements and test methods for dried *Rehmannia glutinosa* root that is derived from *Rehmannia glutinosa* Libosch.

Fresh *Rehmannia glutinosa* Libosch. and processed *Rehmannia glutinosa* Libosch. are excluded.

This document is applicable to *Rehmannia glutinosa* root that is sold and used as a natural medicine in international trade, including Chinese materia medica (whole medicinal materials) and decoction pieces derived from this plant.

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

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

ISO 22217, *Traditional Chinese medicine — Storage requirements for raw materials and decoction pieces*

ISO 22258, *Traditional Chinese medicine — Determination of pesticide residues in natural products by gas chromatography*

ISO 22590, *Traditional Chinese medicine — Determination of sulfur dioxide in natural products by titration*

ISO 23193, *Traditional Chinese medicine — Lycium barbarum and Lycium chinense fruit*

ISO 23723, *Traditional Chinese medicine — General requirements for herbal raw material and materia medica*

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

root

main underground part of *Rehmannia glutinosa* Libosch.

3.2

root weight

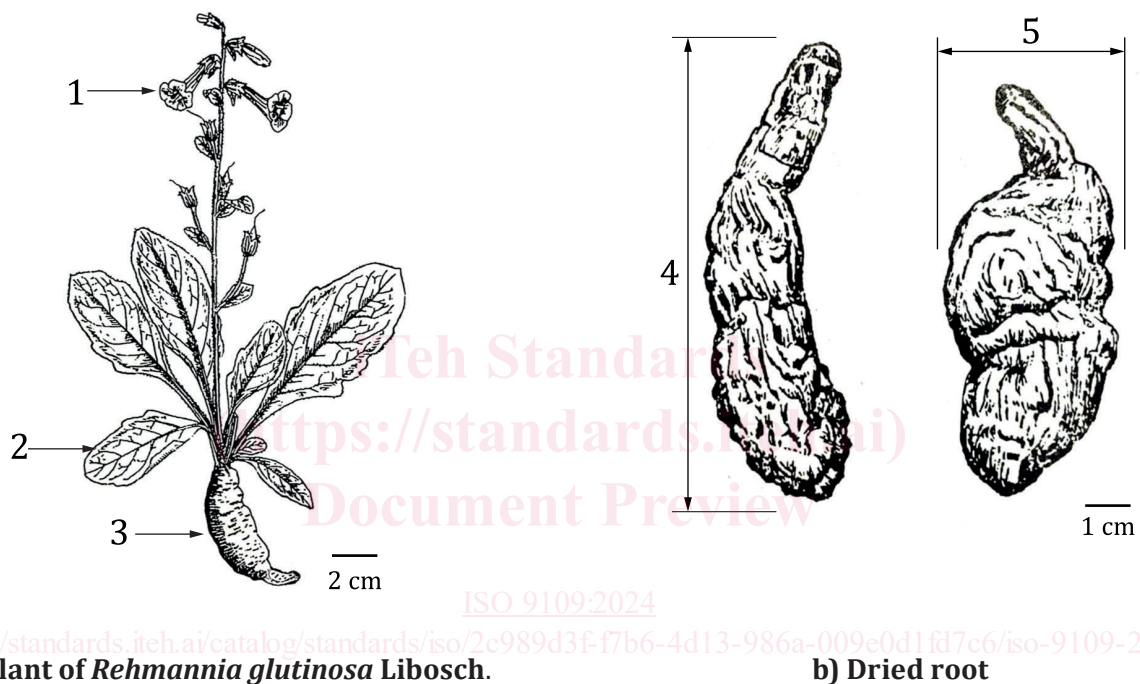
average weight of final samples of root, calculated by sampling no less than 1 000 g from each batch randomly, weighing the roots one by one, and then calculating the average weight of the roots

[SOURCE: ISO 20409:2017, 3.2, modified — details on how to calculate root weight have been added.]

Note 1 to entry: Final samples may be packed in different materials meeting conditions for specific tests (e.g. moisture or total ash).

4 Description

Rehmannia glutinosa root is the dried root of *Rehmannia glutinosa* Libosch. (Fam. Scrophulariaceae), as shown in [Figure 1](#).



Key

1	flower	4	length
2	leaf	5	diameter
3	root		

Figure 1 — Structure of *Rehmannia glutinosa* Libosch.

5 Requirements

5.1 General characteristics

The following requirements shall be met before sampling:

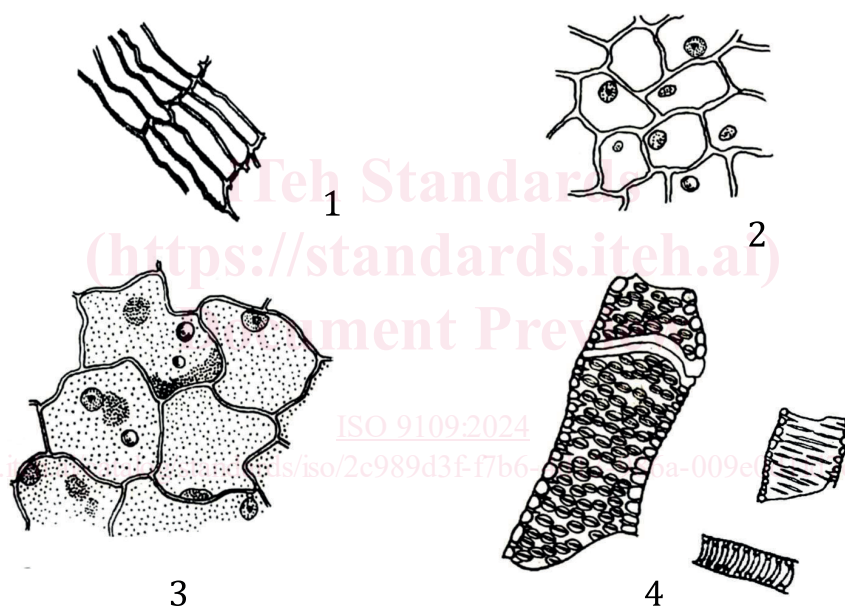
- Rehmannia glutinosa* root shall be clean and free of foreign matter.
- The presence of living insects, mouldy root and external contaminants which are visible to the naked eye shall not be permitted.

5.2 Morphological characteristics

- The roots are an irregular mass or oblong, swollen in the centre, slightly tapering at both ends; some are small, slit-shaped, slightly compressed or twisted, with an irregular transverse flexure.
- The external surface is brownish-black or brownish-grey.
- The root is 6 cm to 12 cm in length and 2 cm to 6 cm in diameter, measured at the base of the root.
- The texture is soft and thick, but libriform, not easily broken.
- The fracture is brownish-yellow to black or jet-black, shiny, with viscosity.
- The odour is slight and the taste is slightly sweet.

5.3 Microscopic characteristics

The powder is dark brown. Cork cells are brownish. Parenchymatous cells are sub-rounded, containing a sub-rounded nuclei-like substance. Secretory cells are similar to parenchymatous cells in shape, containing orange-yellow or orange-red oil droplets. Bordered pitted and reticulated vessels, shown in [Figure 2](#), are up to about 92 µm in diameter.



Key

- cork cells
- parenchymatous cells
- secretory cells
- bordered pitted and reticulated vessels

Figure 2 — Structure of powdered *Rehmannia glutinosa* root

5.4 Moisture

The mass fraction of moisture should be determined.

5.5 Total ash

The mass fraction of total ash should not be more than 8,0 %.

5.6 Acid-insoluble ash

The mass fraction of total ash should not be more than 3,0 %.

5.7 Water-soluble extractives

The mass fraction of water-soluble extractives should be determined.

5.8 Thin-layer chromatogram (TLC) identification

The identification of marker compounds such as catalpol and verbascoside with a thin-layer chromatogram (TLC) should present the spots or bands obtained from the test and reference solutions in the same positions with the same colours.

5.9 Content of marker compounds

The content of marker compounds such as catalpol and rehmannioside D should be determined.

5.10 Heavy metals

The contents of heavy metals such as arsenic, mercury, lead and cadmium shall be determined.

5.11 Pesticide residues

The contents of pesticide residues such as hexachlorocyclohexane, dichlorodiphenyltrichloroethane (DDT) and pentachloronitrobenzene shall be determined.

5.12 Sulfur dioxide residues

The content of sulfur dioxide residues should be determined.

5.13 Grading

If the commercial grades are needed, see [Annex E](#) for additional information.

6 Sampling

Sampling of *Rehmannia glutinosa* root shall be carried out in accordance with the method specified in ISO 23723.

7 Test methods

7.1 Macroscopic identification

Take samples of not less than 1 000 g from each batch randomly. Examine these samples with the naked eye, smell and taste.

7.2 Determination of moisture

The testing method specified in ISO 23723 shall apply.

7.3 Determination of total ash

The testing method specified in ISO 23723 shall apply.