

ISO/FDIS 9109:~~2023~~(E)

ISO/TC 249

Secretariat: SAC

Date: 2023-~~07-28~~09-15

Traditional Chinese medicine — *Rehmannia glutinosa* root

Médecine traditionnelle chinoise — Racine de Rehmannia glutinosa

iTeh STANDARD PREVIEW

(standards.iteh.ai)
FDIS stage

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

© ISO 2023

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~~E-mail: copyright@iso.org

Website: www.iso.org

Published in Switzerland

iTeh STANDARD PREVIEW (standards.iteh.ai)

ISO/FDIS 9109

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

iTeh STANDARD PREVIEW (standards.iteh.ai)

ISO/FDIS 9109

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

Contents

Forewordvi

Introduction.....vii

1 Scope 1

2 Normative references..... 1

3 Terms and definitions 1

4 Description 2

5 Requirements 4

5.1 General characteristics 4

5.2 Morphological characteristics 4

5.3 Microscopic characteristics 4

5.4 Moisture..... 5

5.5 Total ash..... 5

5.6 Acid-insoluble ash..... 5

5.7 Water-soluble extractives 5

5.8 Thin-layer chromatogram (TLC) identification..... 6

5.9 Content of marker compounds..... 6

5.10 Heavy metals..... 6

5.11 Pesticide residues 6

5.12 Sulfur dioxide residues 6

5.13 Grading..... 6

6 Sampling 6

7 Test methods 6

7.1 Macroscopic identification..... 6

7.2 Determination of moisture 6

7.3 Determination of total ash 6

7.4 Determination of acid-insoluble ash..... 6

7.5 Determination of water-soluble extractives..... 6

7.6 Thin-layer chromatogram (TLC) identification..... 7

7.7 Determination of marker compounds..... 7

7.8 Determination of heavy metals 7

7.9 Determination of pesticide residues..... 7

7.10 Determination of sulfur dioxide residues 7

8 Test report 7

9 Packaging, storage and transportation 7

10	Marking and labelling.....	7
Annex A (informative)	Identification of catalpol	9
A.1	Preparation of test solution	9
A.2	Preparation of reference solution	9
A.3	Developing solvent system	9
A.4	Procedure	9
Annex B (informative)	Identification of verbascoside.....	11
B.1	Preparation of test solution	11
B.2	Preparation of reference solution.....	11
B.3	Developing solvent system	11
B.4	Procedure	11
Annex C (informative)	Determination of catalpol content.....	13
C.1	Preparation of reference standard solution	13
C.2	Preparation of test solution	13
C.3	Chromatographic system.....	13
C.4	Content calculation of catalpol	14
Annex D (informative)	Determination of rehmnnioside D.....	17
D.1	Preparation of reference standard solution	17
D.2	Preparation of test solution	17
D.3	Chromatographic system.....	17
D.4	Content calculation of rehmnnioside D.....	18
Annex E (informative)	Example of traditional grading of <i>Rehmannia glutinosa</i> root	21
Annex F (informative)	National and regional requirements for <i>Rehmannia glutinosa</i> root.....	22
	Bibliography	24

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 ~~document~~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.

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, namely, 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~~5.4~~, 5.5~~5.5~~, 5.5 and 5.6~~5.6~~ in their national standards. Examples of national and regional values are given in Annex F~~Annex F~~.

iTeh STANDARD PREVIEW (standards.iteh.ai)

ISO/FDIS 9109

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

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, ~~samples of not~~calculated by sampling no less than 1 000 g ~~are taken~~ from each batch randomly, weighing the roots ~~are weighed~~ one by one, and then calculating the average weight of ~~samples is then calculated~~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).

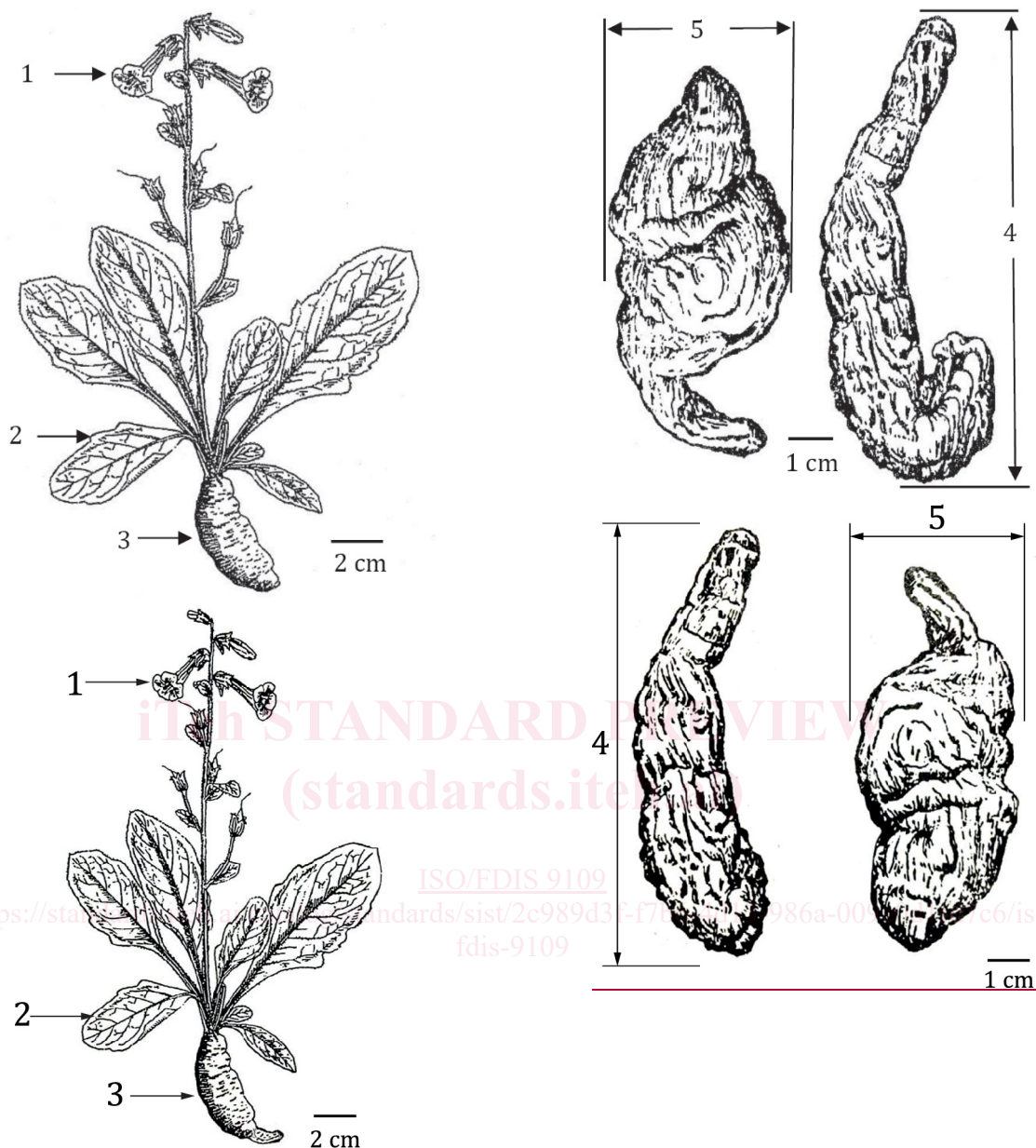
4 Description

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

iTeh STANDARD PREVIEW
(standards.iteh.ai)

ISO/FDIS 9109

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



a) Plant of *Rehmannia glutinosa* Libosch.

b) Dried root

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:

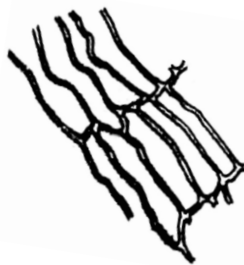
- a) ~~a)~~ *Rehmannia glutinosa* root shall be clean and free of foreign matter.
- b) ~~b)~~ The presence of living insects, mouldy root and external contaminants which are visible to the naked eye shall not be permitted.

5.2 Morphological characteristics

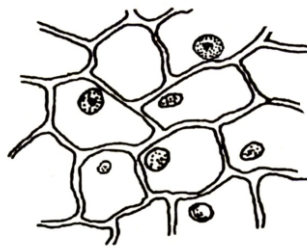
- a) ~~a)~~ The roots are an irregular mass or oblong, swollen in the centre, slightly tapering at both ends; some are small, spat-shaped, slightly compressed or twisted, with an irregular transverse flexure.
- b) ~~b)~~ The external surface is brownish-black or brownish-grey.
- c) ~~c)~~ The root is 6 cm to 12 cm in length and 2 cm to 6 cm in diameter, measured at the base of the root.
- d) ~~d)~~ The texture is soft and thick, but libriform, not easily broken.
- e) ~~e)~~ The fracture is brownish-yellow to black or jet-black, shiny, with viscosity.
- f) ~~f)~~ 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, ~~as shown in Figure 2~~.



1



2



4

