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Traditional Chinese medicine — *Rehmannia glutinosa* root

Médecine traditionnelle chinoise — Racine de Rehmannia glutinosa

Reference number
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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

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.

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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 glutinos*a Libosch.

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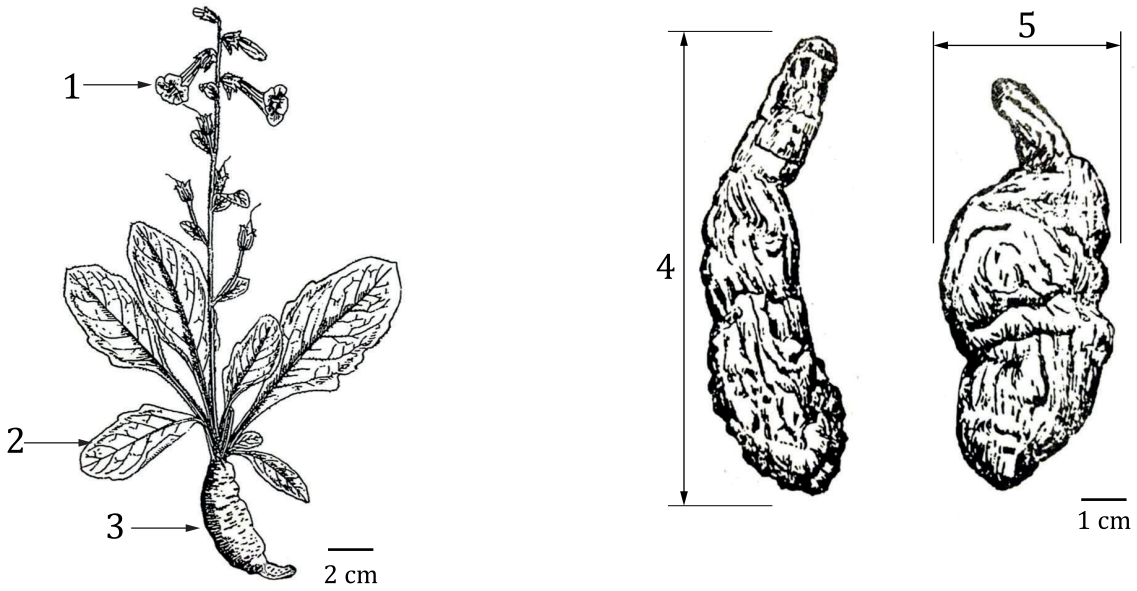
3.2
root weight
average weight of final samples of root, calculated by sampling no less than 1 000 g from each batch randomly, weighing the roots one by one, and then calculating the average weight of the roots

[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.



a) Plant of *Rehmannia glutinosa* Libosch. **b) Dried root**

Key

1 flower
2 leaf
3 root
4 length
5 diameter

Figure 1 — Structure of *Rehmannia glutinosa* Libosch.

5 Requirements

5.1 General characteristics

The following requirements shall be met before sampling:

a) *Rehmannia glutinosa* root shall be clean and free of foreign matter.

b) The presence of living insects, mouldy root and external contaminants which are visible to the naked eye shall not be permitted.

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5.2 Morphological characteristics

a) The roots are an irregular mass or oblong, swollen in the centre, slightly tapering at both ends; some are small, slat-shaped, slightly compressed or twisted, with an irregular transverse flexure.

b) The external surface is brownish-black or brownish-grey.

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.

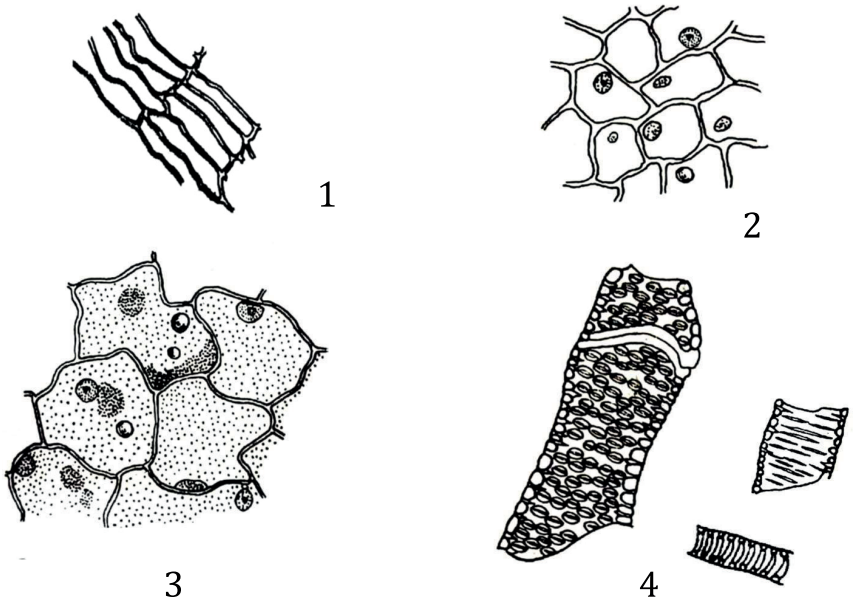
d) The texture is soft and thick, but libriform, not easily broken.

e) The fracture is brownish-yellow to black or jet-black, shiny, with viscosity.

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.



Key

1 cork cells

2 parenchymatous cells

3 secretory cells

4 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 %.

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