



DPC: 25/30498818 DC

BSI Group Headquarters

389 Chiswick High Road London W4 4AL

Tel: +44 (0)20 8996 9000

Fax: +44 (0)20 8996 7400

www.bsigroup.com

Date: 02 April 2025

Origin: International

Latest date for receipt of comments: 26 May 2025

Project No. 2024/02309

Responsible committee: CH/100/1 Traditional Chinese Medicine

Interested committees:

Title: Draft BS ISO 25003 Traditional Chinese medicine - Gentiana scabra, Gentiana manshurica, and Gentiana triflora root and rhizome.

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Introduction

This draft standard is based on national and international discussions. Your comments on this draft are invited and will assist in the preparation of the consequent standard.

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Submission of Comments

- **Annotated drafts are not acceptable and will be rejected.**
- All comments should be submitted online at <https://standardsdevelopment.bsigroup.com/>. You will need to register in order to comment.

Template for comments and secretariat observations

Date: xx/xx/20xx	Document: ISO/DIS xxxx
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1	2	(3)	4	5	(6)	7
MB	Clause No./ Subclause No./Annex (e.g. 3.1)	Paragraph/ Figure/Table/Note	Type of comment	Comment (justification for change) by the MB	Proposed change by the MB	Secretariat observations on each comment submitted
	3.1	Definition 1	ed	Definition is ambiguous and needs clarifying.	Amend to read '...so that the mains connector to which no connection...'	
	6.4	Paragraph 2	te	The use of the UV photometer as an alternative cannot be supported as serious problems have been encountered in its use in the UK.	Delete reference to UV photometer.	



DRAFT International Standard

ISO/DIS 25003

Traditional Chinese medicine — *Gentiana scabra*, *Gentiana manshurica*, and *Gentiana triflora* root and rhizome

ICS: 11.120.10

ISO/TC 249

Secretariat: **SAC**

Voting begins on:
2025-04-02

Voting terminates on:
2025-06-25

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Reference number
ISO/DIS 25003:2025(en)

Full document details: 25/30498818 DC

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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 Descriptions	2
5 Requirements	2
5.1 Morphological features	2
5.2 Microscopic identification	3
5.2.1 Transverse section	3
5.2.2 Powder	3
5.3 Moisture	4
5.4 Total ash	4
5.5 Acid-insoluble ash	4
5.6 Water-soluble extractives	4
5.7 Thin-layer chromatogram identification	4
5.8 Marker compound	4
5.9 Heavy metals	5
5.10 Pesticide residues	5
5.11 Sulfur dioxide	5
6 Sampling	5
7 Test methods	5
7.1 Macroscopic identification	5
7.2 Microscopic identification	5
7.3 Determination of moisture content	5
7.4 Determination of total ash content	5
7.5 Determination of acid-insoluble ash content	5
7.6 Determination of water-soluble extractives content	5
7.7 Thin-layer chromatogram identification	5
7.8 Determination of marker compound	5
7.9 Determination of heavy metals content	5
7.10 Determination of pesticide residues content	6
7.11 Determination of sulfur dioxide contents	6
8 Test report	6
9 Packaging, storage and transportation	6
10 Marking and labelling	6
Annex A (informative) Determination of water-soluble extractives	7
Annex B (informative) Thin-layer chromatogram identification	8
Annex C (informative) Determination of gentiopicroside by HPLC-UV	9
Annex D (informative) Referenced information of national and regional requirements	11
Annex E (informative) Referenced information for differentiating <i>Gentiana scabra</i> Bunge, <i>Gentiana manshurica</i> Kitagawa, and <i>Gentiana triflora</i> Palls	13
Bibliography	16

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 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

Gentiana scabra, *Gentiana manshurica*, and *Gentiana triflora* root and rhizome is the dried root and rhizome of *Gentiana scabra* Bunge, *G. manshurica* Kitagawa, and *G. triflora* Palls (Fam. Gentianaceae), which is known as *Longdan* in China. *Gentiana scabra*, *Gentiana manshurica*, and *Gentiana triflora* root and rhizome is a commonly used Chinese herbal medicine with a long history and is documented in *ShenNong's materia medica*. It has a long history of medicinal use in East Asian countries and is traditionally valued and reported for eliminate damp-heat and quench fire of the liver and gallbladder.

Clinically, it is applied in cases of jaundice, prolonged erection, eczema accompanied with itching, bloodshot eyes, poor hearing, pain in the costal regions and bitter taste in the mouth, convulsion, etc. There are about 500 preparations and formulae containing *Gentiana scabra*, *Gentiana manshurica*, and *Gentiana triflora* root and rhizome and there is a 10 % increase on the demand for *Gentiana* root and rhizome in the Chinese Materia Medica market at home and abroad, about 2,400 tons per year nowadays.

In terms of quality supervision of medicinal materials, the quality and safety of *Gentiana scabra*, *Gentiana manshurica*, and *Gentiana triflora* root and rhizome are regulated in the Pharmacopeia of the People's Republic of China, Japanese Pharmacopoeia, Korean Pharmacopoeia and Hong Kong Chinese Materia Medica Standards. However, the requirements are not all the same among these pharmacopoeias and standards. The standards of *Gentiana scabra*, *Gentiana manshurica*, and *Gentiana triflora* root and rhizome have not yet been unified at the international level, leading to the supervision being different by the regulatory authorities in many countries.

In addition, *Gentiana scabra*, *Gentiana manshurica*, and *Gentiana triflora* root and rhizome is ranked 48th in the ISO/TR 23975: 2019 *Traditional Chinese medicine — Priority list of single herbal medicines for developing standards*, which indicates its high priority. Therefore, it is necessary to establish an international standard of *Gentiana scabra*, *Gentiana manshurica*, and *Gentiana triflora* root and rhizome, which unifies the quality and safety of *Gentiana scabra*, *Gentiana manshurica*, and *Gentiana triflora* root and rhizome, ensures the safety and effectiveness of the medication, and regulates trade in the international market.

This document aims to establish an international standard for *Gentiana scabra*, *Gentiana manshurica*, and *Gentiana triflora* root and rhizome to guarantee the clinical effectiveness, safety, and controllability of this valuable medicine in global commerce and trade.

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

