International Standard

ISO 25003

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

Médecine traditionnelle chinoise — Rhizome et racine de Gentiana scabra, Gentiana manshurica *et* Gentiana triflora

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Foreword

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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 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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This document was prepared by Technical Committee ISO/TC 249, *Traditional medicine*, Subcommittee SC 1, *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

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 (龙胆 in Chinese) 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 Divine Farmer's materia medica. It has a long history of medicinal use in East Asian countries and is traditionally valued and reported to eliminate damp-heat and quench fire of the liver and gallbladder.

Clinically, *Gentiana scabra*, *Gentiana manshurica*, and *Gentiana triflora* root and rhizome 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 in the demand for *Gentiana* root and rhizome in the Chinese materia medica market at home and abroad, about 2, 400 tons per year.

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 85th in ISO/TR 23975, 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.

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

1 Scope

This document specifies the quality and safety requirements of *Gentiana scabra*, *Gentiana manshurica*, and *Gentiana triflora* root and rhizome.

This document applies to *Gentiana scabra*, *Gentiana manshurica*, and *Gentiana triflora* root and rhizome that is sold and used as natural medicines in international trade, including in Chinese materia medica, in its whole medicinal material, and in decoction pieces derived from these plants.

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/TS 21310, *Traditional Chinese medicine — Microscopic examination of medicinal herbs*

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 23723:2021, *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
marker compound
chemical constituent within a medicinal herb that can be used to verify its quality

Note 1 to entry: Usually described as active ingredients or chemicals that confirm the correct botanical identity of the starting material.

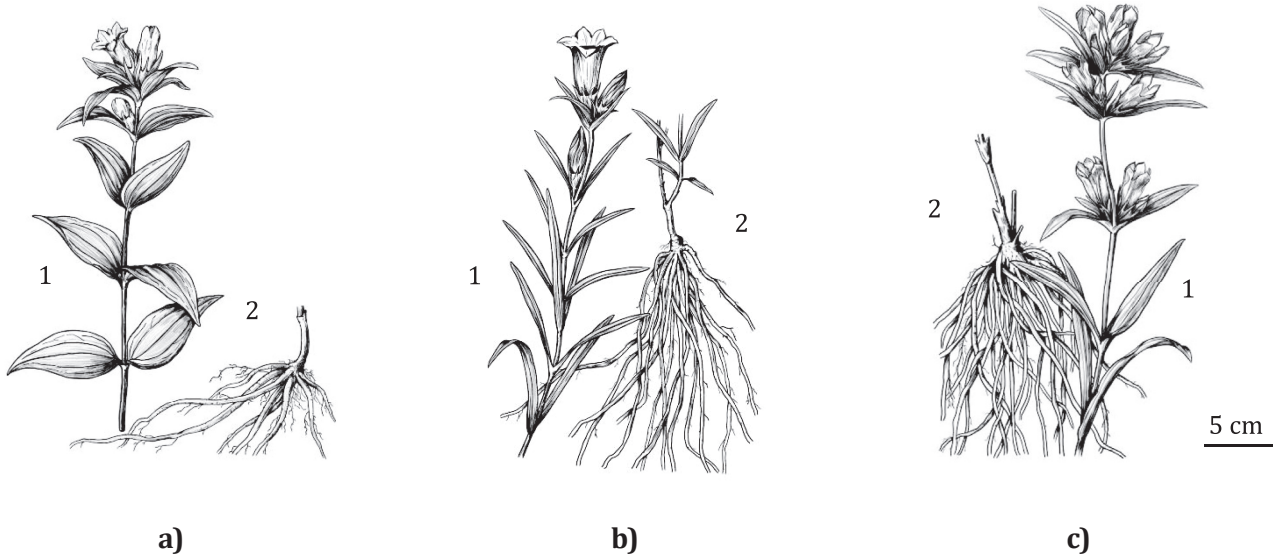
Note 2 to entry: There can be one or more marker compounds for a medicinal herb.

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4 Descriptions

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 (see Figure 1) collected in the spring and autumn. Referenced information for differentiating the three species are given in Annex E.



a) **b)** **c)**

Key

a	plant of *Gentiana scabra* Bunge
b	plant of *Gentiana manshurica* Kitagawa
c	plant of *Gentiana triflora* Palls
1	aerial part
2	root and rhizome

Figure 1 — Structure of the plants of *Gentiana scabra*, *Gentiana manshurica*, and *Gentiana triflora* root and rhizome

5 Requirements and recommendations

5.1 Morphological features

The rhizome is irregularly bundle-shaped, 1 cm to 3 cm long, 0,3 cm to 1 cm in diameter; the outer surface is dark greyish-brown or dark brown; the upper part is with stem scars or remnants of stems, surroundings and the lower part is bearing numerous slender roots. The root is cylindrical, slightly twisted, 4 cm to 20 cm long, 0,2 cm to 0,5 cm in diameter; the outer surface is pale yellow or yellowish-brown; the upper part is usually with conspicuous transverse wrinkles, and the lower part is narrower and marked with longitudinal wrinkles and rootlet scars. The texture is fragile, easily broken; broken surface is slightly even, bark yellowish-white or yellowish-brown. The xylem is pale in colour. The odour is slight. The taste is very bitter.

5.2 Microscopic identification

5.2.1 Transverse section

The exodermis consists of a layer of cells, the outer walls are slightly thick. The cortex is narrow, often with cleft. The exodermis is distinct, cells are elongated tangentially, and each cell is divided by longitudinal walls into several subsquare small cells. The phloem is broad with cleft. The cambium is indistinct. In the xylem, 5 to 10 vessels form groups. The parenchyma cells contain minute needle crystals of calcium oxalate. The pith is distinct. Figure 2 shows the transverse section.

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