

ISO/FDIS 5106:~~2024(en)~~

ISO/TC 249/~~WG 1~~

Secretariat: SAC

Date: 2024-~~09-30~~11-08

Traditional Chinese medicine—~~—~~— *Polygala tenuifolia* and *Polygala sibirica* root

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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 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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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

Polygala root is the dried root of *Polygala tenuifolia* Willd. or *Polygala sibirica* L. (Polygalaceae). It has the functions of soothing the nerves, promoting heart and kidney health, removing phlegm, and reducing swelling. It is used for insomnia, dreaminess, trance, uncomfortable expectoration, sore swelling, breast swelling and pain. The medicinal materials, decoction pieces and extracts of Polygala root are widely sold in China, Japan, Republic of Korea, Southeast Asia, North America and other regions. Polygala root has been included in Chinese Pharmacopoeia, Japanese Pharmacopoeia, Korean Pharmacopoeia and European Pharmacopoeia, but their requirements and test methods are different. Besides, there are traditional Chinese medicine (TCM) such as *Liriope spicata* root on the market, which is usually confused with Polygala root; and the aflatoxins in Polygala root may exceed the maximum residue limit if stored improperly. In addition, the grade of medicinal materials is not linked to the intrinsic quality. These problems can affect the international trade of Polygala root. Therefore, it is necessary to establish an International Standard to bring benefits to the consumers, enterprises and companies involved in the processing, management and trade of *Polygala tenuifolia* and *Polygala sibirica* root, and ensure its quality and safety.

As national implementation can differ, national standards bodies are invited to modify the values given in 5.5.5 in their national standards. Examples of national and regional values are given in Annex C.

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Traditional Chinese medicine——*Polygala tenuifolia* and *Polygala sibirica* root

1 Scope

This document specifies the minimum requirements and test methods for *Polygala tenuifolia* and *Polygala sibirica* root.

It applies to *Polygala tenuifolia* and *Polygala sibirica* root that are sold and used as natural medicines in international trade, including Chinese materia medica (whole medicinal materials) and decoction pieces.

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 15378, *Primary packaging materials for medicinal products — Particular requirements for the application of ISO 9001:2015, with reference to good manufacturing practice (GMP)*

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 22283, *Traditional Chinese medicine — Determination of aflatoxins in natural products by LC-FLD*

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, *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 ~~3.1~~ root

~~the~~ part of a higher plant growing under the stem in the soil

3.2 3.2**Polygala root**

root (3.1) of *Polygala tenuifolia* Willd. or *Polygala sibirica* L.

3.3 3.3**powder**

fine particles of matter in a solid state

3.4 3.4**total ash**

residue obtained after incineration at $525\text{ }^{\circ}\text{C} \pm 25\text{ }^{\circ}\text{C}$

[SOURCE: ISO 22584:2019, 3.3]

3.5 3.5**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.

[SOURCE: ~~ISO~~ISO 22586:2022, 3.2], modified — Note 2 to entry has been removed.]

3.6 3.6**reference medicine**

authentic medicine from the *Polygala root* (3.2(3.1)), used for reference in TLC analyses of the sample

3.7 3.7**sample batch**

samples collected from the same particular place at the same time

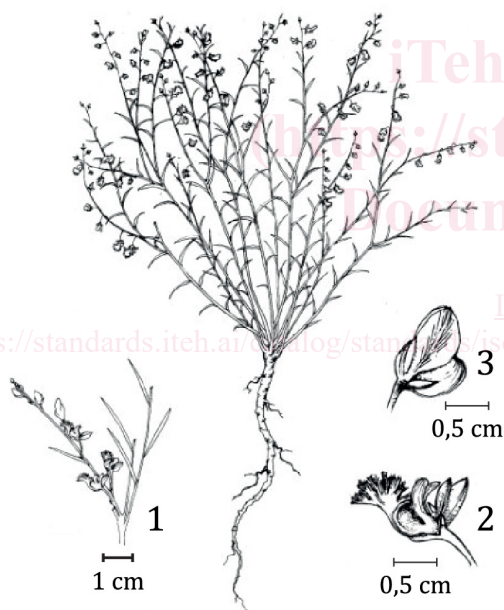
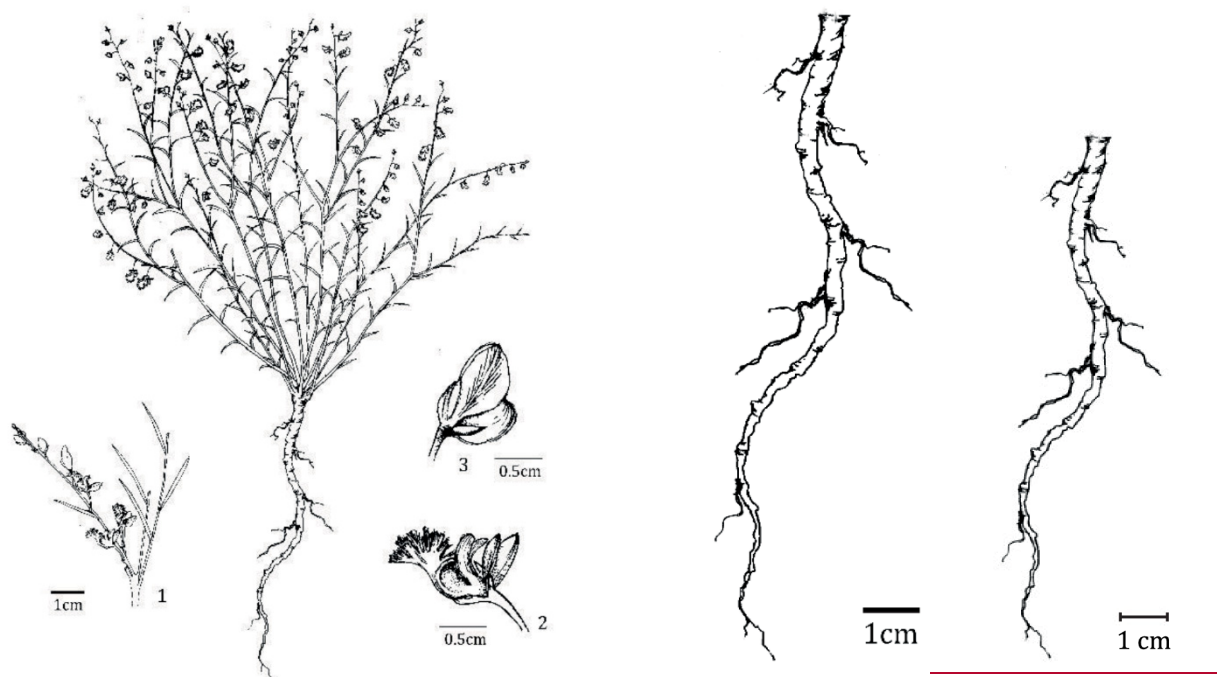
[SOURCE: ISO 21317:2019, 3.5]

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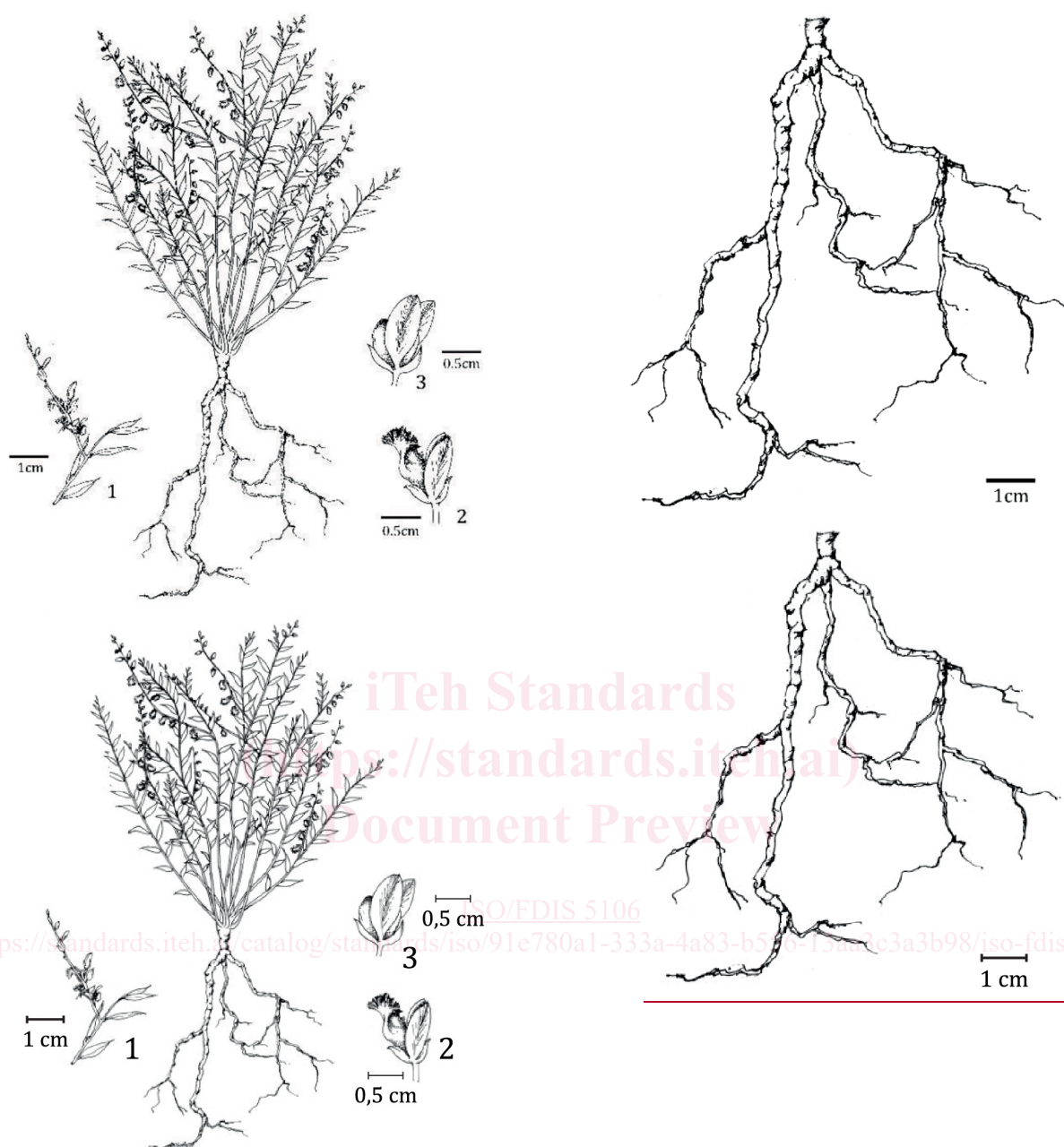
4 Description

Polygala root is the dried root of *Polygala tenuifolia* Willd. and *Polygala sibirica* L. in the family of *Polygalaceae* as shown in [Figure 1](#) ~~Figure 1.~~



a) Plant of *Polygala tenuifolia* Willd.

b) *Polygala tenuifolia* root

c) Plant of *Polygala sibirica* L.d) *Polygala sibirica* root**Key**

- 1 flowering branch
- 2 flower
- 3 fruit

Figure 1 — Morphological structure of *Polygala tenuifolia* and *Polygala sibirica* root**5 Quality and safety requirements and recommendations****5.1 General characteristics**

The following requirements shall be met before sampling.