FINAL DRAFT International Standard

ISO/FDIS 5106

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

ISO/TC **249**

Secretariat: **SAC**

Voting begins on:
2024-11-25

Voting terminates on:
2025-01-20

Reference number
ISO/FDIS 5106:2024(en)

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

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Foreword

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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 in their national standards. Examples of national and regional values are given in Annex C.

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

3.2
***Polygala* root**
root (3.1) of *Polygala tenuifolia* Willd. or *Polygala sibirica* L.

3.3
powder
fine particles of matter in a solid state

3.4
total ash
residue obtained after incineration at 525 °C ± 25 °C

[SOURCE: ISO 22584:2019, 3.3]

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

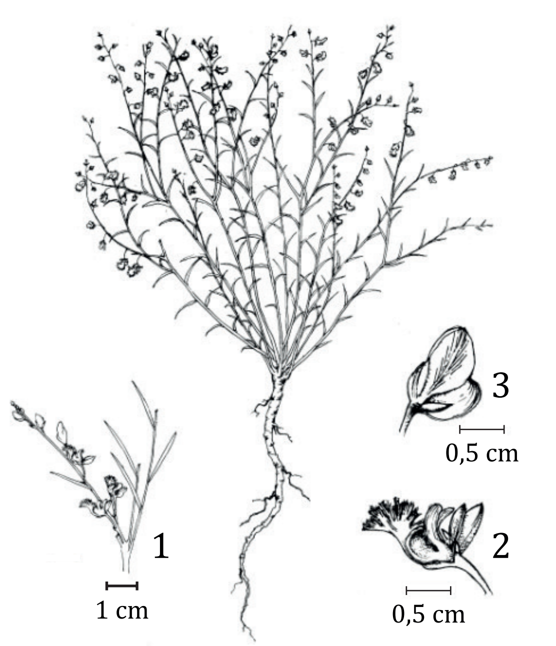
3.6
reference medicine
authentic medicine from the *Polygala root* (3.2), used for reference in TLC analyses of the sample

3.7
sample batch
samples collected from the same particular place at the same time

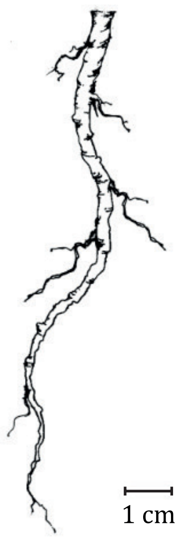
[SOURCE: ISO 21317:2019, 3.5]

4 Description

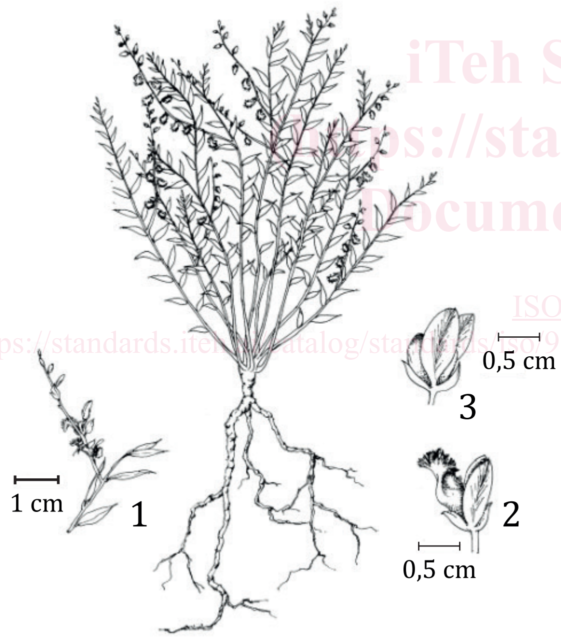
Polygala root is the dried root of *Polygala tenuifolia* Willd. and *Polygala sibirica* L. in the family of *Polygalaceae* as shown in Figure 1.



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.

a) *Polygala tenuifolia* and *Polygala sibirica* root materials shall be dry.

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

5.2 Macroscopic characteristics

Polygala tenuifolia root is cylindrical, long, thin and curved. The main root is 2 cm to 30 cm in length and 0,2 cm to 1 cm in diameter. The external surface is pale greyish yellow to greyish brown with a relatively dense and deeply dented transverse wrinkles, longitudinal wrinkles and open gaps. Older roots have relatively dense transverse wrinkles, even more deeply dented, slightly knotted. The texture is hard, fragile and easy to cut. The cut surface has a yellowish-brown cortex and yellowish-white xylem. The cortex and xylem are separate and easily detached, sometimes with the core already removed.

Different from *Polygala tenuifolia* root, *Polygala sibirica* root is forked more.

Polygala root has a faint odour and a slightly acrid taste.

5.3 Microscopic characteristics

5.3.1 Transverse section

The transverse section of *Polygala tenuifolia* root reveals a cork layer consisting of about 10 rows of cork cells. The cortex is narrow and the phloem is relatively wide with open gaps throughout. The cambium forms a ring. Those from which the core has not been removed have a xylem. Several vessels form groups and are scattered, surrounded by lignified xylem fibre bundles. The xylem rays consist of 1 to 3 rows of cells, most parenchyma cells contain fatty oil drops, sometimes containing calcium oxalate druses or solitary crystals.

For *Polygala sibirica* root, the outside of xylem is flat, without awn tooth structure.

5.3.2 Powder

The *P. tenuifolia* powder shows the following diagnostic characters:

a) fragments of lignified tissue made up of numerous pitted tracheids and slightly larger, reticulate, pitted or bordered-pitted vessels;

b) yellowish parenchyma cells containing oil droplets;

c) fragments of cork, sometimes accompanied by phelloderm and parenchyma, some cells of which contain oil droplets;

d) numerous isolated oil droplets;

e) *P. tenuifolia* powder also containing calcium oxalate cluster crystals, isolated or included in parenchymatous cells;

f) long, fine, thick-walled lignified fibres, most often fragmented, in clusters or associated with vessels.

For *Polygala sibirica* root powder, there are abundant round granules in the inner layer of thrombus, but no oil droplets.