International Standard

ISO 25661

Traditional Chinese medicine — *Polygonatum kingianum*, *Polygonatum sibiricum*, and *Polygonatum cyrtonema* rhizome

Médecine traditionnelle chinoise — Rhizome de Polygonatum kingianum, Polygonatum sibiricum *et* Polygonatum cyrtonema

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Foreword

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Introduction

Polygonati rhizome (Huang Jing) is the dried rhizome of *Polygonatum kingianum* Collett & Hemsl., *Polygonatum sibiricum* Redouté, and *Polygonatum cyrtonema* Hua (Fam. Liliaceace). It is found in China, Korea, Japan, Vietnam, Myanmar, Laos, Thailand, Mongolia, and eastern Siberia, Russia. The dried rhizome of *Polygonatum falcatum* A. Gray is also used as Polygonati rhizome in Japanese Pharmacopoeia and Korean Pharmacopoeia.

Polygonati rhizome has been commonly consumed as a health food supplement and in traditional Chinese medicine (TCM) for thousands of years due to high nutritional and medicinal values. In Mingyi Bielu (220 AD to 450 AD), a classic medical text from ancient China, Polygonati rhizome was recorded as one of extremely valuable herbs. According to the traditional Chinese medicine theory, Polygonati rhizome has the functions of tonifying the Qi and the Yin, strengthening the spleen, moistening the lung and tonifying the kidney. Modern pharmacological studies have shown that Polygonati rhizome not only has the effects of lowering blood sugar, lowering blood lipids, anti-oxidation, anti-cancer, anti-inflammation and antibacterial, but also has the pharmacological effects of anti-fatigue, immune regulation and anti-aging. This is related to the rich chemical components of Polygonati rhizome, such as polysaccharide, saponins, flavonoids, alkaloids and amino acids. Along with a growing number of studies on Polygonati rhizome, various beneficial nutrients within Polygonati rhizome are being proposed, including carbohydrate, dietary fibre, mineral, vitamin, sugar, amino acid, fatty acid and protein. Thus, Polygonati rhizome is considered as a popular nutritious food and herb worldwide.

Polygonati rhizome as a special medicinal and edible material, has a lot of international attention and demand. Searching publications on Polygonati rhizome in the PubMed database for the past ten years reveals that more than 25 countries and regions have carried out relevant research. The global average annual trade volume of Polygonati rhizome from 2018 to 2022 was about 5 962 t, and the global average annual trade value is about 57,43 million US dollars. The world's main export countries of Polygonati rhizome are concentrated in China, Myanmar and India. Among them, China and Myanmar account for about 95,1 % of the world's annual exports. The main import countries and regions of Polygonati rhizome are: Japan, South Korea, Hong Kong, Taiwan, Vietnam, Malaysia, the United States, Singapore, Thailand, Germany, Ireland, France, New Zealand, Spain, Canada, Australia, Italy, Indonesia, Sudan, the Netherlands, the Russian Federation, India, the United Kingdom, etc. According to Chinese customs data, China's export trade volume of Polygonati rhizome was 2 809 t (in 2018), 2 911 t (in 2019), 3 399 t (in 2020), 6 236 t (in 2021) and 7 001 t (in 2022) with an annual average export trade value of about 45,57 million US dollars. The analysis of international trade data shows that the growing demand for Polygonati rhizome in the global market has provided a market basis for the development of a Polygonati rhizome International Standard.

However, the quality of Polygonati rhizome provided from different areas or by different cultivators varies a lot. Although Polygonati rhizome has been recorded in Chinese Pharmacopoeia, Japanese Pharmacopoeia, Korean pharmacopoeia and Hong Kong Chinese Medicinal Material Standards, these standards are not harmonized and can be unsuitable for the purpose of international trade of Polygonati rhizome. Thus, there is a clear and urgent need to develop an International Standard for harmonizing the existing standards, as well as ensuring the safety and quality of Polygonati rhizome.

As national implementation can differ, national standards bodies can modify the values given in 5.7 in their national standards. Examples of national and regional values are given in Annex C.

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Traditional Chinese medicine — *Polygonatum kingianum*, *Polygonatum sibiricum*, and *Polygonatum cyrtonema* rhizome

1 Scope

This document specifies the requirements and test methods for Polygonati rhizome, which is derived from the plant of *Polygonatum kingianum* Collett & Hemsl., *Polygonatum sibiricum* Redouté, and *Polygonatum cyrtonema* Hua (Fam. Liliaceace).

This document is applicable to Polygonati rhizome that is sold and used as herbal raw materials in the 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/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 22283, *Traditional Chinese medicine — Determination of aflatoxins in natural products by LC-FLD*

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*

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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
Polygonati rhizome
dried rhizome of *Polygonatum kingianum* Collett & Hemsl., *Polygonatum sibiricum* Redouté, and *Polygonatum cyrtonema* Hua (Fam. Liliaceace)

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