
**Traditional Chinese medicine —
Dendrobium officinale stem**

Médecine traditionnelle chinoise — Tige de Dendrobium officinale

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ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Fax: +41 22 749 09 47
Email: copyright@iso.org
Website: www.iso.org

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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 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).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

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

Dendrobium officinale stem, the dried stem of *Dendrobium officinale* Kimura et Migo, is a widely used herb medicine in China and many other Asian countries. In traditional Chinese medicine, this herb is used to treat fever, retching and excessive thirst. Modern pharmacological studies also demonstrate its great potential in diabetes treatment and immuno-enhancement. Therefore, the market for *Dendrobium officinale* has developed very rapidly, as indicated by the increase in yield, production output and trade volume.

However, there remain many challenges, such as adulteration of similar species and lack of suitable testing methods for quality assessment. In addition, though *Dendrobium officinale* has been recorded in several pharmacopoeias and standards, such as Chinese Pharmacopoeia^[4], Hong Kong Chinese Materia Medica Standards^[5] and Taiwan Herbal Pharmacopoeia^[6], specifications and quality requirements of these standards vary, 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 effectiveness of *Dendrobium officinale*.

As national implementation may differ, National Standards Bodies are invited to modify the values given in 5.2.3, 5.2.4 and 5.2.5 in their national standards. Examples of national and regional values are given in Annex E.

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Traditional Chinese medicine — *Dendrobium officinale* stem

1 Scope

This document specifies minimum requirements and test methods for *Dendrobium officinale* stem that is derived from cultivated *Dendrobium officinale* Kimura et Migo.

It is applicable to *Dendrobium officinale* stem that is sold and used as 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 1575, *Tea — Determination of total ash*

ISO 18664, *Traditional Chinese Medicine — Determination of heavy metals in herbal medicines used in Traditional Chinese Medicine*

ISO 20409, *Traditional Chinese medicine — Panax notoginseng root and rhizome*

ISO 21371, *Traditional Chinese medicine — Labelling requirements of products intended for oral or topical use*

CAC/MRL01, *Maximum Residue Limits for Pesticides in Foods*

CODEX STAN 229, *Analysis of pesticide residues: Recommended methods*

World Health Organization. *Quality control methods for herbal materials, General advice on sampling*, 2011

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- ISO Online browsing platform: available at <https://www.iso.org/obp>
- IEC Electropedia: available at <http://www.electropedia.org/>

3.1 fresh stem

stem that is newly harvested and has not undergone any processing

3.2 dried stem

stem prepared by cleaning, cutting and then heating or sun-drying

3.3 processed stem

stem processed by trimming off the fibrous root and leaves, stir-baking while twisting to a spiral or spring form and drying

Note 1 to entry: This is the common trade form of dried stem of *Dendrobium officinale*. It is usually called Tie Pi Feng Dou in Chinese.

4 Descriptions

Dendrobium officinale stem generally has three trade forms, including fresh stem, dried stem and processed stem (Tie Pi Feng Dou), as shown in [Figure 1](#).



- Key**
- 1 node
 - 2 leaf sheath

Figure 1 — Structure of *Dendrobium officinale*

5 Requirements

5.1 General characteristics

The following requirements shall be met before sampling:

- a) *Dendrobium officinale* stem shall be clean and free from foreign matter.

- b) The presence of living insects, moulds and external contaminants which are visible to the naked eye shall not be permitted.

5.2 *Dendrobium officinale* stem

5.2.1 Morphological features

5.2.1.1 Fresh stem

Cylindrical, circular for cross section. Nodes distinct, unbranched. Purple-dotted leaf sheath. Externally yellowish-green, striated longitudinally. Odour slight. Taste mild, then sweet and viscous on chewing.

5.2.1.2 Dried stem

Cylindrical, differ in length. Externally greyish-green, yellowish-green or golden yellow, striated longitudinally, sometimes grey leaf sheath remained. Odour slight. Taste mild, then viscous on chewing.

5.2.1.3 Processed stem

Spiral or spring-like, usually with two to six spires. Texture compact, easily broken, fracture even, grey to greyish-green. Externally yellowish-green or golden yellow, striated longitudinally, sometimes grey leaf sheath remained. Odour slight. Taste mild, then viscous on chewing.

5.2.2 Thin-layer chromatogram (TLC) identification

The identification of *Dendrobium officinale* stem by thin-layer chromatogram (TLC) shall present spots or bands with the same colour and position corresponding to those of reference standard solution.

5.2.3 Moisture <https://standards.iteh.ai/catalog/standards/sist/cf4bd998-7e9b-46aa-b481-9a7f2a6f9e1d/iso-21370-2019>

The mass fraction of moisture should not be more than 14,0 %.

NOTE The fresh stem is exempt from this test.

5.2.4 Total ash

The mass fraction of total ash should not be more than 7,0 %.

NOTE The fresh stem is exempt from this test.

5.2.5 Ethanol-soluble extractives

The mass fraction of ethanol-soluble extractives should not be less than 5,0 %.

NOTE The fresh stem is exempt from this test.

5.2.6 Marker compounds

Marker compounds such as polysaccharides, mannose and peak area ratio of mannose to glucose shall be determined.

NOTE The fresh stem is dried before testing.

5.2.7 Heavy metals

The content of heavy metals such as arsenic, mercury, lead and cadmium shall be determined.

5.2.8 Pesticide residues

The content of pesticide residues such as Benzex, DDT (dichloro-diphenyl-trichloroethane) and quintozene shall be determined.

6 Sampling

Sampling of *Dendrobium officinale* stem shall be in accordance with the World Health Organization's *Quality control methods for herbal materials*.

7 Test methods

7.1 Macroscopic identification

Samples not less than 500 g are taken from each batch randomly. These samples are examined by the naked eye, smell and taste.

7.2 TLC identification

See [Annex A](#) for additional information.

7.3 Determination of moisture content

The testing method specified in ISO 20409 shall apply.

7.4 Determination of total ash

The testing method specified in ISO 1575 shall apply.

7.5 Determination of ethanol-soluble extractives

See [Annex B](#) for additional information.

7.6 Determination of marker compounds

See [Annexes C](#) and [D](#) for additional information.

7.7 Determination of heavy metals

The testing method specified in ISO 18664 shall apply.

7.8 Determination of pesticide residues

The testing method specified in CODEX STAN 229 and CAC/MRL01 shall apply.

8 Test report

For each test method, the test report shall specify the following:

- a) all information necessary for the complete identification of the sample;
- b) the sampling method used;
- c) the test method(s) used;
- d) the test result(s) obtained;

- e) all operating details not specified in this document, or regarded as optional, together with details of any incidents which may have influenced the test result(s);
- f) any unusual features (anomalies) observed during the test;
- g) the date of the test.

9 Packaging, storage and transportation

The packaging shall not transmit any odour or flavour to the product and shall not contain substances which may damage the product or constitute a health risk.

The product shall be stored in a dry and cool place.

The product shall be protected from light, moisture, pollution and the entry of foreign substances during long-distance delivery.

10 Marking and labelling

The requirements specified in ISO 21371 shall apply. The following items shall be marked or labelled on the packages:

- a) product name;
- b) category of the product in the marketed country or region;
- c) net mass/quantity;
- d) contact information;
- e) name of raw materials;
- f) warning statements, if any;
- g) expiry date;
- h) storage method;
- i) batch/lot number;
- j) CITES conformity;
- k) miscellaneous.

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