# FINAL DRAFT International Standard

# ISO/FDIS 8959

# Traditional Chinese medicine — *Eucommia ulmoides* stem bark

ISO/TC **249**

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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 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

*Eucommia ulmoides* stem bark has the effects of nourishing the liver and kidneys and strengthening bones. It is recorded in *Compendium of Materia Medica* and *Sheng Nong's herbal classic*, and is clinically used in the treatment of hypertension, chronic kidney disease, arthritis and other diseases. Various commodity specifications of *Eucommia ulmoides* stem bark, including its medicinal materials, decoction pieces and extracts, are widely traded in China, the Republic of Korea, Japan, Malaysia, Vietnam, Singapore, Thailand, Canada and the United States of America. Although *Eucommia ulmoides* stem bark has been included in several national pharmacopoeias and regional standards, the requirements differ. In addition, there are many problems with *Eucommia ulmoides* stem bark products on the market, such as mixed use of non-medicinal parts and irregular processing, which can lead to a decline in the quality of this medicinal herb. Therefore, it is necessary to establish a unified International Standard to guarantee the quality and safety of *Eucommia ulmoides* stem bark.

As national implementation can 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 C.

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# Traditional Chinese medicine — *Eucommia ulmoides* stem bark

## 1 Scope

This document specifies the minimum requirements and test methods for *Eucommia ulmoides* stem bark.

It is applicable to *Eucommia ulmoides* stem bark that is sold and used as natural medicines in international trade, including Chinese materia medica (whole medicinal materials) and raw decoction pieces.

It is not applicable to processed decoction pieces of *Eucommia ulmoides* stem bark.

## 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 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, *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**
***Eucommia ulmoides* stem bark**
outer covering of the stem of *Eucommia ulmoides* Oliv.

**3.2**
**reference medicine**
authentic medicine from *Eucommia ulmoides stem bark* (3.1) used for reference in thin-layer chromatographic analyses of the sample

**3.3**
**batch**
samples collected from the same particular place at the same time

[SOURCE: ISO 21317:2019, 3.5]

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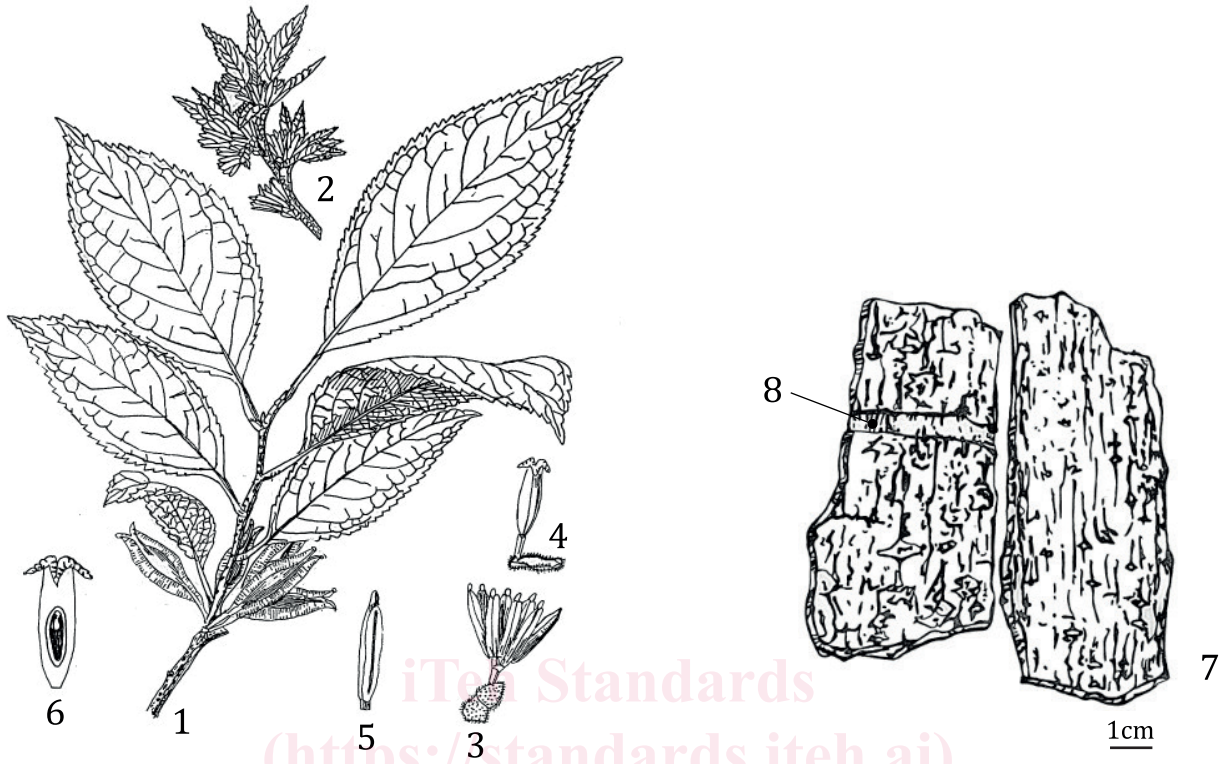
# 4 Descriptions

*Eucommia ulmoides* stem bark is the dried stem bark of *Eucommia ulmoides* Oliv. in the family of Eucommiaceae, as shown in Figure 1.

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**Key**

1 fruiting branch
2 flowering branch
3 male flower
4 female flower
5 stamen lateral view
6 ovary longitudinal section
7 stem bark
8 rubber thread

**Figure 1 — Structure of *Eucommia ulmoides* stem bark**

# 5 Requirements

## 5.1 General characteristics

The following requirements shall be met before sampling:

a) *Eucommia ulmoides* stem bark shall be clean and dry.

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

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## 5.2 Macroscopic characteristics

They are in flat pieces or the two edges somewhat curved inward, varying in size and 0,3 cm to 0,7 cm thick. The outer surface is pale brown or greyish-brown, markedly wrinkled or fissured and channelled longitudinally. Some pieces are relatively thin, showing distinct lenticels when the coarse bark is unscraped. The inner surface is dark purple and smooth. The texture is fragile, easily broken, fracture linked by fine, dense, silvery, elastic and resinous threads. The odour is slight and the taste is slightly bitter.

## 5.3 Microscopic characteristics

### 5.3.1 Transverse section

The transverse section sometimes shows evidence of rhytidome outside the cork cells. Cork consists of several rows of cells. Phloem consists of five to seven bands of lignified stone cells; each band contains two to six rows of stone cells, with fibres nearby. Phloem rays are two to three cells wide. Resinous masses are scattered.

### 5.3.2 Powder

The colour is brown. The resinous threads are stripe-shaped or twisted into masses, the surface granular. Sclereids are numerous, mostly in groups, subrectangular to subrounded, elongated-rectangular or irregular, 20 µm to 80 µm in diameter, up to 180 µm long and thick-walled, with some containing resinous masses. Cork cells are polygonal in surface view, 15 µm to 40 µm in diameter, with unevenly thickened, lignified and finely pitted walls; rectangular in lateral view, walls thicker on three sides and relatively thin on one side, pit canals distinct. See Figure 2.

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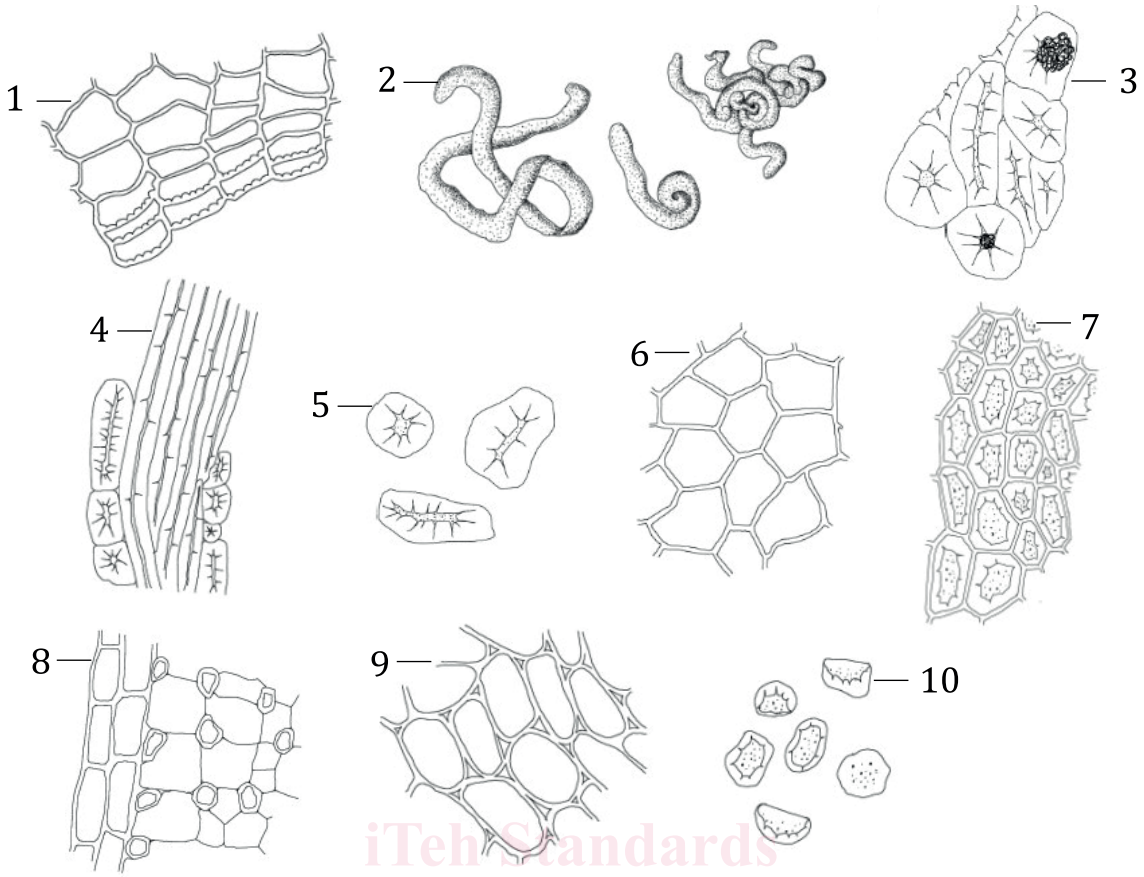


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**Key**

1 cork consisting of layers of cells
2 ribbon-shaped latex fragments
3 sclereids in groups
4 fibres in groups associated with sclereids
5 isolated sclereids
6 cork consisting of polygonal cells
7 hard cork consisting of polygonal cells
8 rare fragments of phloem parenchyma
9 ovoid parenchyma cells
10 isolated hard cork cells

**Figure 2 — Microscopic characteristics of *Eucommia ulmoides* stem bark powder**

## 5.4 Moisture

The mass fraction of moisture should not be more than 13,0 %.

## 5.5 Total ash

The mass fraction of total ash content should not be more than 10,0 %.

## 5.6 Acid-insoluble ash

The mass fraction of acid insoluble ash should be determined.

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