**FINAL DRAFT** 

## INTERNATIONAL **STANDARD**

**ISO/FDIS** 20759

ISO/TC 249

Secretariat: SAC

Voting begins on: 2023-09-20

Voting terminates on:

2023-11-15

### Traditional Chinese medicine — Artemisia argyi leaf

*Médecine traditionnelle Chinoise* — Artemisia argyi *feuille* 

RECIPIENTS OF THIS DRAFT ARE INVITED TO SUBMIT, WITH THEIR COMMENTS, NOTIFICATION OF ANY RELEVANT PATENT RIGHTS OF WHICH THEY ARE AWARE AND TO PROVIDE SUPPORTING DOCUMENTATION.

IN ADDITION TO THEIR EVALUATION AS BEING ACCEPTABLE FOR INDUSTRIAL, TECHNOLOGICAL, COMMERCIAL AND USER PURPOSES, DRAFT INTERNATIONAL STANDARDS MAY ON OCCASION HAVE TO BE CONSIDERED IN THE LIGHT OF THEIR POTENTIAL TO BECOME STAN-DARDS TO WHICH REFERENCE MAY BE MADE IN NATIONAL REGULATIONS.



Reference number ISO/FDIS 20759:2023(E)

# iTeh STANDARD PREVIEW (standards.iteh.ai)

ISO/FDIS 20759
https://standards.iteh.ai/catalog/standards/sist/bc00a1f8-f332-4d59-b22a-a773479b2e12/iso-fdis-20759



#### **COPYRIGHT PROTECTED DOCUMENT**

© ISO 2023

All rights reserved. Unless otherwise specified, or required in the context of its implementation, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

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

Con	tents	Page
Forev	vord	iv
Intro	luction	v
1	Scope	
_	•	
2	Normative references	
3	Terms and definitions	1
4	Description	2
5	Requirements and recommendations	3
	5.1 General characteristics	
	5.2 Macroscopic characteristics	3
	5.3 Microscopic characteristics	
	5.4 Thin layer chromatogram	4
	5.5 Volatile oil and 1,8-cineole (C <sub>10</sub> H <sub>18</sub> O) content	
	5.6 Total flavonoids content	5
	5.7 Dilute ethanol-soluble extract	
	5.8 Moisture content	5
	5.9 Total ash	5
	5.10 Acid-insoluble ash	5
6	Sampling	5
	Test methods	_
7		
	7.1 Macroscopic identification	
	7.2 Microscopic identification	
	7.3 Thin-layer chromatographic identification	
	7.4 Determinations of volatile oil content and 1,8-cineole( $C_{10}H_{18}O$ ) content	6
	7.5 Determination of total flavonoids content	
	7.6 Determination of dilute ethanol-soluble extract 118-1332-4d59-b22a-	
	7.7 Determination of moisture content 0 dis-20759	
	7.8 Determination of total ash	
	7.9 Determination of acid-insoluble ash	6
8	Test report	6
9	Packaging, storage and transportation	7
10	Marking and labelling	7
Anne	x A (normative) Thin layer chromatographic identification of Artemisia argyi leaf	
Anne	x B (normative) Determination of volatile oil and 1,8-cineole contents in Artemisia argyi leaf	10
Anne	x C (normative) Determination of total flavonoids content in Artemisia argyi leaf	12
Anne	D (informative) Limit values of 1,8-cineole, dilute ethanol-soluble extract, moisture, total ash and acid-insoluble ash of mugwort leaf (Artemisia argyi leaf) in pharmacopoeias of different countries and regions	13
Anne	x E (informative) Habitat, cultivation, harvesting and processing of Artemisia argyi Lévl. et Vant	
Biblio	graphy	

#### 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 <a href="www.iso.org/directives">www.iso.org/directives</a>).

ISO draws attention to the possibility that the implementation of this document may involve the use of (a) patent(s). ISO takes no position concerning the evidence, validity or applicability of any claimed patent rights in respect thereof. As of the date of publication of this document, ISO had not received notice of (a) patent(s) which may be required to implement this document. However, implementers are cautioned that this may not represent the latest information, which may be obtained from the patent database available at <a href="www.iso.org/patents">www.iso.org/patents</a>. ISO shall not be held responsible for identifying any or all such patent rights.

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 <a href="https://www.iso.org/iso/foreword.html">www.iso.org/iso/foreword.html</a>.

This document was prepared by Technical Committee ISO/TC 249, Traditional Chinese medicine.

This second edition cancels and replaces the first edition (ISO 20759:2017), of which it constitutes a minor revision. The changes are as follows:

- in 3.6, cross-reference to 7.7 corrected to 7.6;
- <u>Clause 10</u> g) removed to comply with updated drafting rules;
- in <u>Annex D</u>, edition dates of the Chinese Pharmacopoeia and the Taiwan Herbal Pharmacopoeia updated; all data from the Japanese Pharmacopoeia removed due to difference of the original plant of mugwort leaf;
- minor editorial changes.

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 <a href="https://www.iso.org/members.html">www.iso.org/members.html</a>.

#### Introduction

Mugwort leaf is a traditional herbal medicine. It is mainly used for the treatment of irregular menstruation, infertility, hematemesis, epistaxis, metrorrhagia and pruritus in China and some other countries. It is also the raw material for the famous moxibustion therapy, many pharmaceutical preparations and healthcare products. Mugwort leaf originates from the three species of plants *Artemisia argyi* Lévl. et Vant., *Artemisia princeps* Pampanini and *Artemisia montana* Pampanini. The three original species mainly grow in China and Korea, and the second and third species also grow in Japan. Among them, the dried leaf of *Artemisia argyi* Lévl. et Vant. has been used most extensively worldwide. This document was developed mainly to control the quality of *Artemisia argyi* leaf for direct medicinal and pharmaceutical purposes.

For reference, the limit values of the relevant target substance and moisture, total ash and acidinsoluble ash have been provided in <u>Annex D</u>. In addition, factors affecting the quality of *Artemisia argyi* leaf include pH and organic matters of soil, light, harvest time, as well as cultivation techniques. These factors cannot be controlled by sample analysis. Therefore, relevant information is described in <u>Annex E</u> as a reference.

## iTeh STANDARD PREVIEW (standards.iteh.ai)

ISO/FDIS 20759
https://standards.iteh.ai/catalog/standards/sist/bc00a1f8-f332-4d59-b22a-a773479b2e12/iso-fdis-20759

## iTeh STANDARD PREVIEW (standards.iteh.ai)

**ISO/FDIS 20759** 

https://standards.iteh.ai/catalog/standards/sist/bc00a1f8-f332-4d59-b22a-a773479b2e12/iso-fdis-20759

### Traditional Chinese medicine — Artemisia argyi leaf

#### 1 Scope

This document specifies the minimum requirements and test methods of *Artemisia argyi* leaf for medicinal use. It is suitable for identification and quality control of this herbal medicine.

#### 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 928, Spices and condiments — Determination of total ash

ISO 930, Spices and condiments — Determination of acid-insoluble ash

ISO 939, Spices and condiments — Determination of moisture content

ISO 6571, Spices, condiments and herbs — Determination of volatile oil content (hydrodistillation method)

#### 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 <a href="https://www.iso.org/obp">https://www.iso.org/obp</a>
- IEC Electropedia: available at <a href="https://www.electropedia.org/">https://www.electropedia.org/</a>

#### 3.1

#### Artemisia argyi leaf

dried leaf of the plant Artemisia argyi Lévl. et Vant., which belongs to the family Asteraceae

#### 3.2

#### reference medicine

authentic medicine from the dried leaf of *Artemisia argyi* Lévl. et Vant., used for reference in thin layer chromatogram analyses of the sample

#### 3.3

#### volatile oil content

substances in the sample entrained by steam under the conditions specified in **Annex B** 

Note 1 to entry: It is expressed in ml per 100 g of dry duct.

[SOURCE: ISO 6571:2008, 3.1, modified — Definition revised.]

#### 3.4

#### 1,8-cineole content

mass fraction of 1,8-cineole ( $C_{10}H_{18}O$ ) in the sample determined in accordance with the method of Annex B

#### 3.5

#### total flavonoids content

mass fraction of the total flavonoids in the sample determined in accordance with the method in  $\underline{\text{Annex C}}$ 

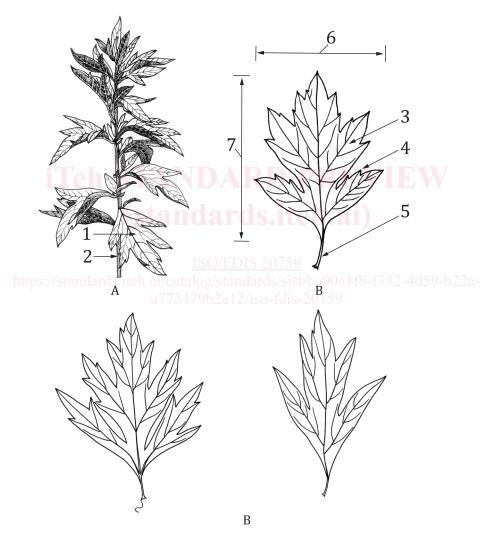
#### 3.6

#### dilute ethanol-soluble extract

extract obtained from the sample determined in accordance with the method specified in 7.6

### 4 Description

In this document, *Artemisia argyi* leaf is the dried leaf from the plant *Artemisia argyi* Lévl. et Vant. (see <u>Figure 1</u> A) and consists of leaf blade and petiole (see <u>Figure 1</u> B).



#### Key

- A plant of Artemisia argyi Lévl. et Vant.
- B leaves of the middle stem of *Artemisia argyi* Lévl. et Vant.
- 1 leaf blade
- 2 stem
- 3 segment

- 4 dentate segment/wide sawtooth
- 5 petiole
- 6 leaf blade width
- 7 leaf blade length

Figure 1 — Plant of Artemisia argyi Lévl. et Vant. and structure of the leaf

#### 5 Requirements and recommendations

#### 5.1 General characteristics

The following requirements should be met before separating the bulk sample into test samples:

- a) Artermisia argyi leaf shall be clean and free from foreign matter.
- b) The presence of mouldy leaves, external contaminants and living insects which are visible to the naked eye shall not be permitted.

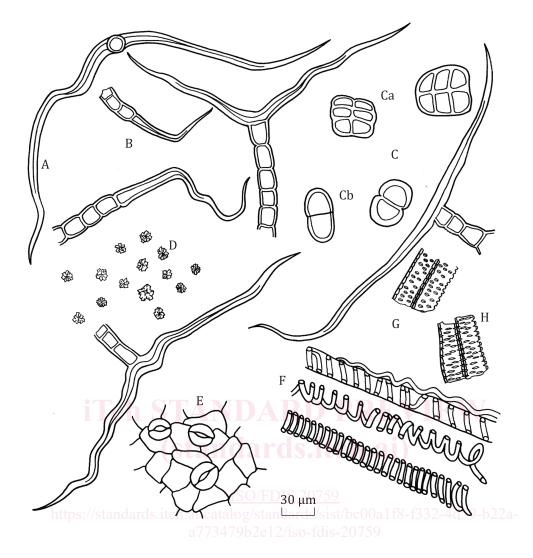
#### 5.2 Macroscopic characteristics

The leaves are mostly crumpled or broken, with short petioles and usually without pseudostipule at the base. The leaf blade is broad ovate, rhombic-ovate or ovate-elliptical, 5 cm to 9(16) cm long, 4 cm to 8(16) cm wide and pinnatipartite to pinnatifid; segments in two or three pairs, elliptical-lanceolate, or elliptical-oblanceolate, frequently 1 cm to 1,5(3) cm wide, with margins irregularly dentate or lobed or wide serrate, dentate piece or wide sawtooth, mostly asymmetrically ovate-lanceolate, ovate-triangular or entire. Smaller leaves are fewer, pinnatipartite, tri-cleft, sometimes entire and elliptical to lanceolate. The upper surface is greyish-green or dark yellowish-green, possessing somewhat sparse pubescences, denser glandular dots and small pits; the lower surface is covered densely with greyish-white tomenta. The petiole is usually 2 mm to 8 mm long and up to 1,3 cm in the cultivated plants.

It has a specific, delicate aroma and a slightly bitter and astringent taste.

#### 5.3 Microscopic characteristics

The powder is greenish-brown. T-shaped hairs (A) are numerous, with a short uniseriate stalk consisting of two to six small cells, and perpendicularly capped by a relatively straight or undulating terminal cell (7  $\mu$ m to 18  $\mu$ m in diameter and up to 980  $\mu$ m long) tapering at the ends. Soft hairs (B) are uniseriate, consisting of three to five cells, with a very long and twisted apical cell, which are frequently broken. Glandular hairs (C), without stalk, consist of four or six oppositely-overlapped cells in lateral view (Ca) and in pairs and paramecium-like in apical view (Cb). Cluster crystals of calcium oxalate (D) are frequently 3  $\mu$ m to 12  $\mu$ m in diameter, mostly occurring in mesophyll cells. Fragments of epidermis in surface view (E) are with anomocytic stomas. Fragments of spiral vessels (F) can be frequently seen; vessels with bordered pit (G) and reticulate vessels (H) are sometimes visible (see Figure 2).



#### Key

- A T-shaped hair
- B uniseriate soft hair
- C glandular hair
- Ca glandular hair in lateral view
- Cb glandular hair in apical view
- D cluster crystal of calcium oxalate
- E fragment of epidermis in surface view
- F spiral vessel
- G vessel with bordered pit
- H reticulate vessel

Figure 2 — Illustration of powdered Artemisia argyi leaf

#### 5.4 Thin layer chromatogram

The chromatogram of the sample solution shall exhibit a purplish-red spot corresponding to caryophyllene oxide at the same Rf value  $(0.55 \pm 0.05)$  as caryophyllene oxide from the reference solution and exhibit main spots with the same colours corresponding to those from the reference medicine solution at the same Rf values.

#### 5.5 Volatile oil and 1,8-cineole ( $C_{10}H_{18}O$ ) content

The volatile oil content and the mass fraction of 1,8-cineole should be detected.

#### 5.6 Total flavonoids content

The mass fraction of total flavonoids, expressed as apigenin  $(C_{15}H_{10}O_5)$ , should be detected.

#### 5.7 Dilute ethanol-soluble extract

The mass fraction of dilute ethanol-soluble extract shall not be less than 12,0 %.

#### 5.8 Moisture content

The mass fraction of moisture shall not be more than 15,0 %.

#### 5.9 Total ash

The mass fraction of total ash shall not be more than 12,0 %.

#### 5.10 Acid-insoluble ash

The mass fraction of acid-insoluble ash shall not be more than 3,0 %.

#### 6 Sampling

The maximum weight of each batch of the material should not be more than 5 000 kg. When a batch consists of two or more containers or packaging units, the container or packaging number of sampling should be based on the World Health Organization's *Quality control methods for herbal materials*, 'General advice on sampling'.[2] Take three original samples from the top, middle and bottom of each container or package selected. These original samples should be combined into a pooled sample and mixed carefully.

The average sample is obtained by quartering. Adequately mix the pooled sample into an even and square-shaped heap and divide it diagonally into four equal parts. Take two diagonally opposite parts and mix carefully. Repeat the process as necessary until the required quantity (not less than 1 000 g) is obtained. Then, using the same quartering procedure, divide the average sample into four final samples, taking care that each portion is representative of the bulk material. Use final samples as the test sample (not less than 250 g) for the measurement and analysis. A portion of each final sample should be retained to serve as reference material, which may also be used for re-test purposes if necessary.

Use cut samples in the experiments, except macroscopic identification and microscopic identification. Before the experiment, the test sample should be cut finely into pieces of about 4 mm<sup>2</sup>, mixed carefully and sealed.

#### 7 Test methods

#### 7.1 Macroscopic identification

Not less than 200 g of the test sample is used to observe with the naked eye. Observe the glandular dots and small pits on the upper surface of the leaf blade by using a stereomicroscope. Smell the odour of the sample, taste its flavour and measure the length and width of the unfolded leaves after immersing them in water.