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Traditional Chinese medicine — *Artemisia argyi* leaf

La médecine traditionnelle Chinoise — Artemisia argyi feuille

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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.

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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 famous moxibustion therapy, many pharmaceutical preparations and health care products. Mugwort leaf originates from the three species of plants *Artemisia argyi* Lévl. et Vant., *Artemisia princeps* Pampanini or *Artemisia montana* Pampanini in different countries. 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 in the world. This document is established mainly to control the quality of *Artemisia argyi* leaf for direct medicinal and pharmaceutical purpose.

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

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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 — Entrainment method

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

3 Terms and definitions (standards.iteh.ai)

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

ISO 20759:2017

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

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

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

3.3

volatile oil content

all the 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 — "in the sample" has been inserted and the term "International Standard" has been replaced with "Annex B".]

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 Annex C

3.6

dilute ethanol-soluble extract

extract obtained from the sample determined in accordance with the method specified in 7.7

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).



Кеу

- 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

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 moldy 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 margin 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, and 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; 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 slightly bitter and astringent taste.

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5.3 Microscopic characteristics (standards.iteh.ai)

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 μ m to 18 μ m in diameter and up to 980 μ 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 μ m to 12 μ 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

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- B uniseriate soft hairC 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 (C₁₀H₁₈O) 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 of packaging units, the container of packaging number of sampling should be based on the World Health Organization: *Quality control methods for herbal materials, General advice on sampling.* 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 mm², mixed carefully and sealed.

7 Test methods

7.1 Macroscopic identification

Not less than 200 g of the test sample is used to observe by the naked eyes. 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 flavor, and measure the length and width of the unfolded leaves after immersing them in water.

7.2 Microscopic identification

Take about 1 mg of the powdered test sample on a glass slide, add two to three drops of chloral hydrate solution, and heat to make the sample object clear while stirring with a small glass rod to prevent boiling. After cooling, add one drop of diluted glycerin, and put a cover glass on it. Then, observe the microscopic characteristics using an optical microscope.