



FINAL DRAFT International Standard

Traditional Chinese medicine — Gardenia jasminoides fruit

*Médecine traditionnelle chinoise — Fruit du Gardenia
jasminoides*

ISO/FDIS 13619

ISO/TC 249

Secretariat: **SAC**

Voting begins on:
2024-03-04

Voting terminates on:
2024-04-29

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Published in Switzerland

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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

Gardenia jasminoides fruit, the dried fruit of *Gardenia jasminoides* Ellis (Fam. Rubiaceae), is widely used in China, Japan, Korea, other Southeast Asian countries and North America, and has a long application history as herbal medicine. It is commonly used for draining fire and treatment of certain febrile conditions, cooling blood and eliminating stasis to activate blood circulation. Clinically, owing to its medicinal properties, it plays an important role in diuretic, cholagogue, anti-inflammatory, antioxidant and antipyretic effects.

Gardenia jasminoides fruit has also been applied as an important natural colourant, such as gardenia yellow and gardenia blue pigments in China, Japan, Korea, India and North America. Recently, there has been an increasing demand for *Gardenia jasminoides* fruit in China and elsewhere; the average annual demand for *Gardenia jasminoides* fruit between 2015 and 2020 was about 1 500 t. *Gardenia jasminoides* fruit is ranked no. 59 in the priority list of single herbal medicines for developing standards in ISO/TR 23975.

Gardenia jasminoides fruit has been widely cultivated as a medicinal and ornamental plant in the tropical and subtropical regions of the world, growing on mountain slopes or at the roadside. However, the quality of *Gardenia jasminoides* fruit cultivated by different areas is quite different. In addition, though *Gardenia jasminoides* fruit has been recorded in several pharmacopeias and standards, specifications and quality requirements in these standards are varied. Thus, there is a clear and urgent need to develop an International Standard for harmonizing these existing standards, as well as ensuring the safety and effectiveness of *Gardenia jasminoides* fruit.

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 D](#).

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Traditional Chinese medicine — *Gardenia jasminoides* fruit

1 Scope

This document specifies the quality and safety requirements and test methods of *Gardenia jasminoides* fruit, which is derived from the dried fruit of *Gardenia jasminoides* Ellis (Fam. Rubiaceae).

This document is applicable to *Gardenia jasminoides* fruit that are sold and used as natural medicines in international trade, including Chinese materia medica (whole medicinal material) 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 23723:2021, *Traditional Chinese medicine — General requirements for herbal raw material and materia medica*

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/>

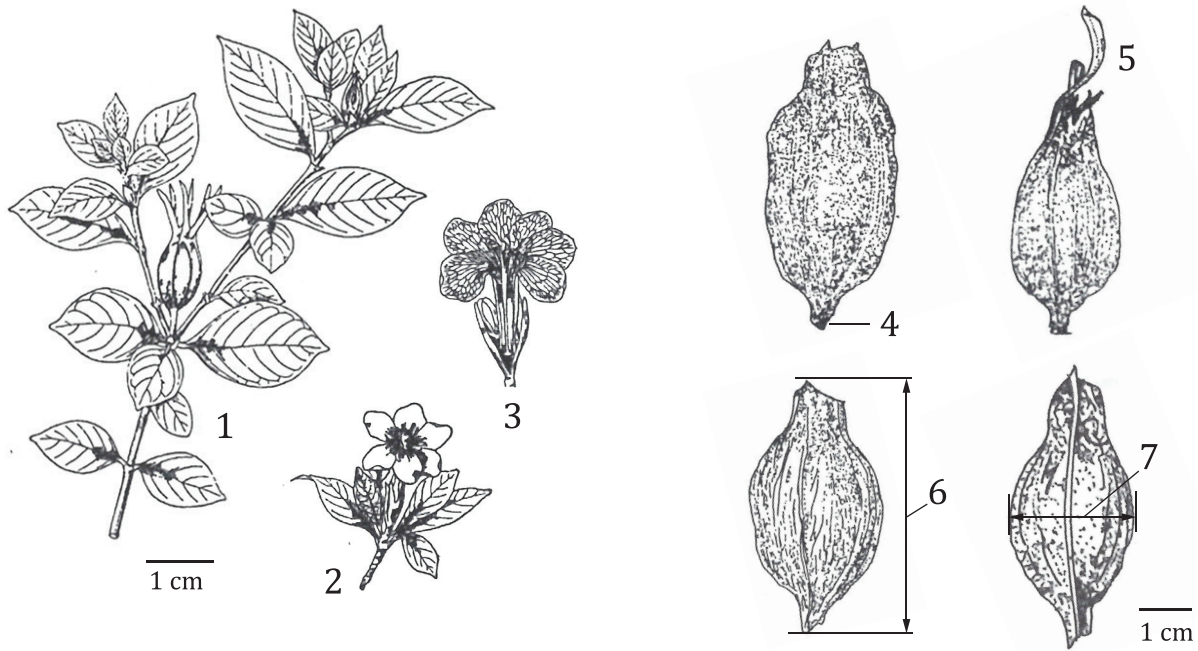
3.1

***Gardenia jasminoides* fruit**

dried ripe fruit of *Gardenia jasminoides* Ellis (Fam. Rubiaceae)

4 Descriptions

In this document, the structure of *Gardenia jasminoides* Ellis and the dried ripe fruit are shown in [Figure 1](#). Different features such as leaves, flowers and fruits in *Gardenia jasminoides* Ellis and *Gardenia jasminoides* var. *grandiflora* Nakai, and methods for differentiating these two species, are given in [Annex C](#).



a) Plant part of *Gardenia jasminoides* Ellis

b) Dried ripe *Gardenia jasminoides* fruit

Key

- 1 fruiting branch
- 2 flowering branch
- 3 corolla and calyx
- 4 peduncle
- 5 persistent calyx
- 6 length
- 7 diameter

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Figure 1 — Structure of the plant part and fruit of *Gardenia jasminoides* Ellis

5 Requirements and recommendations

5.1 General

The following requirements shall be met before the sampling with reference to [Clause 6](#).

- a) *Gardenia jasminoides* fruit shall be clean and free from leaves, stems and foreign matter.
- b) The presence of living inserts, mouldy fruit and external contaminants which are visible to the naked eye shall not be permitted.

5.2 Morphological features

5.2.1 Appearance

The fruit is ovate to long ovate or elliptical (see [Figure 1](#) b). The external fruit surface usually has six antesepalous raised and longitudinal winged ridges. The basally gamosepalous persistent calyx (key 5) or its scar are visible at the upper end of the fruit, and sometimes has the peduncle (key 4) remaining at the

lower end of the fruit. The inner surface of pericarp is brittle, smooth and lustrous, and is internally divided into two or three rows of protruding membranes, which contain seeds.

5.2.2 Colour

The smooth or slightly rough outer surface is yellowish, reddish-yellow or brownish-red. The pericarp has a pale yellow or brownish-yellow inner surface.

5.2.3 Dimensions

The fruit is 15 mm to 35 mm in length measured from the base to the end of the fruit, and 10 mm to 15 mm in diameter measured at the middle of the fruit.

5.2.4 Fracture

The pericarp is thin and easily broken. The seeds are flattened ovate, with several seeds gathered together to form masses. They are deep red or yellowish red, with a dense arrangement of thin, small strumae on the external surface.

5.2.5 Odour and taste

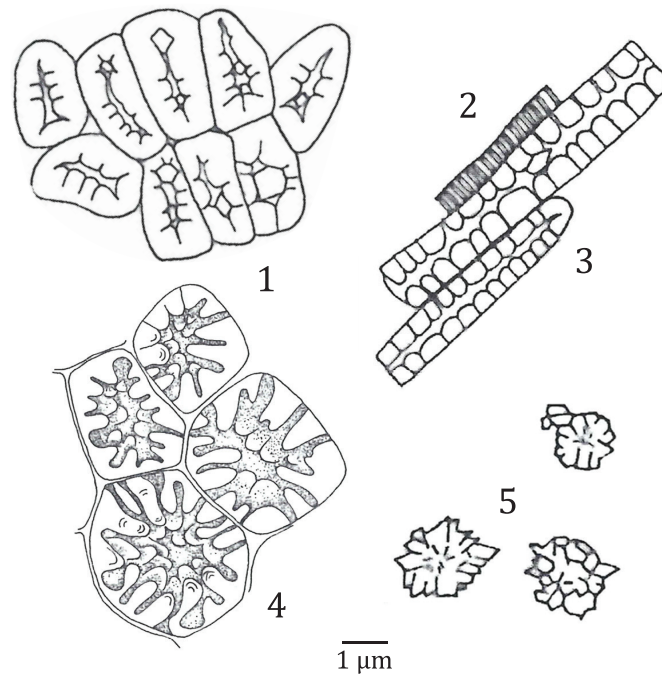
The odour is slight and the taste is bitter.

5.3 Microscopic characteristics

As shown in [Figure 2](#), the powder is reddish-brown or yellowish-brown; sclereid of endocarp (key 1) is subrounded or polygonal, about 17 μm to 31 μm in diameter, with thickened walls and lumina containing crystals of calcium oxalates about 8 μm in diameter; fragments of mesocarp consist of thin-walled parenchymatous cells associated with fibres and yellowish spiral or annular vessels (key 2); endocarp fibres (key 3) are long and thin, about 10 μm in diameter and up to 100 μm long, obliquely mosaic-arranged; fragments of testa consist of largely irregularly shaped sclereids (key 4), 58 μm to 150 μm in diameter and up to 260 μm long, with irregularly thickened yellowish walls, wide pits and containing a reddish-brown substance; and endosperm with cells containing scattered clusters of calcium oxalate (key 5).

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Key

- 1 sclereid of endocarp
- 2 annular vessel
- 3 endocarp fibre
- 4 sclereid of testa
- 5 calcium oxalate

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Figure 2 — Microscopic characteristics of *Gardenia jasminoides* fruit powder

5.4 Moisture

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

5.5 Total ash

The total ash content should not be more than a mass fraction of 6,0 %.

5.6 Thin-layer chromatogram (TLC) identification

The identification of extracts of *Gardenia jasminoides* fruit with thin-layer chromatogram (TLC) should present the spot or band with the same colour and position as those of the reference solution.

5.7 Marker compound(s)

The content of marker compounds, such as geniposide ($C_{17}H_{24}O_{10}$), should be determined.

5.8 Heavy metals

The contents of heavy metals, such as arsenic, mercury, lead and cadmium, should be determined.

5.9 Pesticide residues

The contents of pesticide residues, such as DDT, endrin, BHC, aldrin and dieldrin, should be determined.