International Standard

ISO 13619

Traditional Chinese medicine — *Gardenia jasminoides* fruit

Médecine traditionnelle chinoise — Fruit du Gardenia jasminoides

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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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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.

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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.

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