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Traditional Chinese medicine — Gastrodia elata tuber

Médecine traditionnelle chinoise — Tubercule de Gastrodia elata



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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.

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 documents 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.

Introduction

Gastrodia elata tuber, the dried tuber of *Gastrodia elata* Bl. (Orchidaceae) after it has been steamed thoroughly, is a medicinal herb which has been used as an anticonvulsant, analgesic and sedative to treat general paralysis, epilepsy, tetanus and vertigo in Asian countries for thousands of years.

There are at least 16 countries and regions using *Gastrodia elata* tuber and its products. Major users include China, Japan, South Korea, the United State, Australia, Austria and Singapore. Due to its great demand and high price in the global market, trade in *Gastrodia elata* tuber has been complicated by adulteration, substitution and species identification issues. The toxic roots of other species, such as the plants of the Phytolaccaceae family, are sometimes misused as *Gastrodia elata* tuber, which can cause health risks. Factors including contamination, packaging and storage conditions also affect the quality of *Gastrodia elata* tuber.

The establishment of an international standard for *Gastrodia elata* tuber is therefore necessary to support its quality consistency, clinical effectiveness and safety in international trade.

As national implementation may differ, National Standards Bodies are invited to modify the values given in 5.3, 5.4, 5.5 and 5.7 in their national standards. Examples of national and regional values are na de la companya del companya de la companya del companya de la companya del companya de la companya de la companya de la companya del companya de la companya della companya de la companya de la companya della compa given in Annex F.

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Traditional Chinese medicine — Gastrodia elata tuber

1 Scope

This document specifies minimum requirements and test methods for *Gastrodia elata* tuber that is derived from cultivated and artificially propagated *Gastrodia elata* Bl.

It is applicable to *Gastrodia elata* tuber that is sold and used as Chinese materia medica, specifically excluding the wild forms of the species.

2 Normative references

ISO 1575, Tea — Determination of total ash

ISO 5379, Starches and derived products — Determination of sulfur dioxide content — Acidimetric method and nephelometric method

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

CODEX STAN 229-1993, REV.1-2003, Analysis of pesticide residues: Recommended methods

CAC/MRL01-2009, Maximum Residue Limits for Pesticides in Foods

World Health Organization. 2011, Quality control methods for herbal materials

3 Terms and definitions

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

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

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

3.1

Gastrodia elata tuber

dried tuber of Gastrodia elata Bl. (Orchidaceae) after it has been steamed or boiled thoroughly

3.2

bud

undeveloped or embryonic shoot in red-brown to dark brown, which is parrot-beak-shaped and grows on the apex of the tuber

Note 1 to entry: See Figure 1.

3.3

latent bud

bud which remains undeveloped or dormant, arranged along the body of Gastrodia elata tuber

Note 1 to entry: See Figure 1.