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Traditional Chinese medicine — *Angelica sinensis* root

*Médecine traditionnelle chinoise — Racine d'*Angélique chinoise

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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 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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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 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

Angelica root is a traditional herbal remedy, derived from the dried root of *Angelica sinensis* (Oliv.) Diels, *Angelica acutiloba* (Sieb. et Zucc.) Kitagawa and *Angelica gigas* Nakai, of the Umbelliferae family, as recorded by the Chinese Pharmacopoeia, the Japanese Pharmacopoeia and the Korean Pharmacopoeia, respectively, and has a long medicinal history. *Angelica sinensis* is still one of the herbs most commonly used by traditional Chinese medicine practitioners in Asia, North America and Europe. It is commonly known as female ginseng, and widely used to invigorate blood circulation and replenish blood in treating women's reproductive problems, such as dysmenorrhea, amenorrhoea and menopause. It has also been used in over 20 countries for its significant effectiveness in the pharmaceutical and cosmetic fields.

The quality of *Angelica sinensis* root is crucial for efficacy and safety for consumers. Until now, there have been no unique requirements for *Angelica sinensis* root, although *Angelica sinensis* root has also been recorded by the American Herbal Pharmacopoeia, the European Pharmacopoeia, the British Pharmacopoeia and the Hong Kong Chinese Materia Medica Standards. It is therefore important to standardize the quality of *Angelica sinensis* root globally in order to benefit farmers, enterprises and companies involved in the planting, management and trade of *Angelica sinensis* root.

As national implementation may differ, national standards bodies are invited to modify the values given in 5.4, 5.5, 5.6, 5.7, 5.8, 5.9 and 5.10 in their national standards. Examples of national and regional values are given in Annex D.

Traditional Chinese medicine — *Angelica sinensis* root

1 Scope

This document specifies minimum requirements and test methods for *Angelica sinensis* root that is derived from *Angelica sinensis* (Oliv.) Diels.

It is applicable to *Angelica sinensis* root that is sold and used as a natural medicine in international trade, including Chinese materia medica (whole medicinal materials) 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 1575, *Tea — Determination of total ash*

ISO 1577, *Tea — Determination of acid-insoluble ash*

ISO 18664, *Traditional Chinese Medicine — Determination of heavy metals in herbal medicines used in Traditional Chinese Medicine*

ISO 20409, *Traditional Chinese medicine — Panax notoginseng root and rhizome*

ISO 21371, *Traditional Chinese medicine — Labelling requirements of products intended for oral or topical use*

CAC/MRL01 *Maximum Residue Limits for Pesticides in Foods*

CODEX STAN 229, *Analysis of pesticide residues: Recommended methods*

World Health Organization 2011, *Quality control methods for herbal materials, General advice on sampling*

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
root
main underground part of a plant that can branch

3.2
root stock
top part of the dried main *root* (3.1), which is closest to the stem

3.3
total ash
residue obtained after incineration at 525 °C ± 25 °C