INTERNATIONAL STANDARD

ISO 21316

First edition
2019-02

Traditional Chinese medicine — *Isatis indigotica* root

*Médecine traditionnelle chinoise — Racine d'*Isatis indigotica

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Reference number
ISO 21316:2019(E)

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Published in Switzerland

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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.

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Introduction

Isatis indigotica root, dried root of *Isatis indigotica* Fort. (Fam. Brassicaceae), is one of the most commonly used herbs in traditional Chinese medicine (TCM). It has a long history of use in East Asian countries to remove heat and toxins, cool the blood and clear the throat.

Clinically, *Isatis indigotica* root is recognized as an important traditional Chinese herb for the prevention and treatment of colds and malignant infectious diseases, especially SARS and H1N1. At present, *Isatis indigotica* root and its processed products occupy a huge share of the international market. However, many problems, such as different quality requirements among different countries and regions, adulteration with Baphicacanthis root derived from the dried root and rhizome of *Baphicacanthus cusia* (Nees) Bremek (Fam. Acanthaceae), and different packaging, transportation and storage conditions, can affect the quality of *Isatis indigotica* root.

Therefore, the establishment of an international standard is necessary to establish the quality requirements of *Isatis indigotica* root to support its clinical effectiveness and safety. This document consists of a morphology observation of macroscopic characteristics, phytochemical indexes, and standardized physical and chemical tests (moisture, total ash and acid-insoluble ash). Glucosinolates with multi-bioactivities are specific compositions of the plant in the Brassicaceae family. Among them, (R,S)-goitrin with high specificity reflects bioactivities relevant to the effects of *Isatis indigotica* root. Using (R,S)-goitrin as the marker, TLC identification and HPLC assay methods are established in this document.

As national implementation may differ, National Standards Bodies are invited to modify the values given in 5.2, 5.3, 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 — *Isatis indigotica* root

1 Scope

This document specifies the minimum requirements and test methods for *Isatis indigotica* root derived from the plant *Isatis indigotica* Fort.

It is applicable to *Isatis indigotica* roots that are sold as Chinese material 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, *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
dried root of *Isatis indigotica* Fort. (Fam. Brassicaceae)

3.2
batch
group of samples collected from the same particular place at the same time, no more than 5 000 kg

3.3
final sample
sample for the test required in this document

Note 1 to entry: Final samples may be packed in different materials meeting conditions for specific tests (e.g. moisture or total ash).

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