
**Traditional Chinese medicine — *Isatis
indigotica* root**

Médecine traditionnelle chinoise — Racine d'Isatis indigotica

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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).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

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

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 *Baphicacanthus* 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

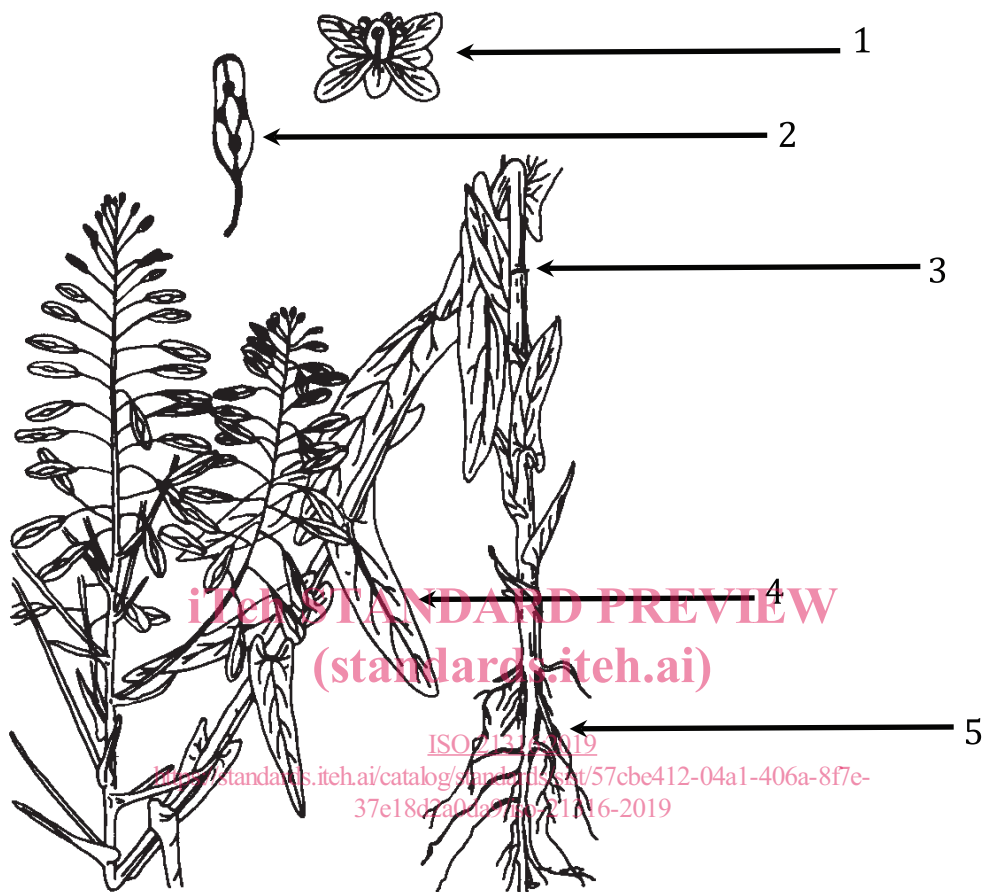
final sample

sample for the test required in this document

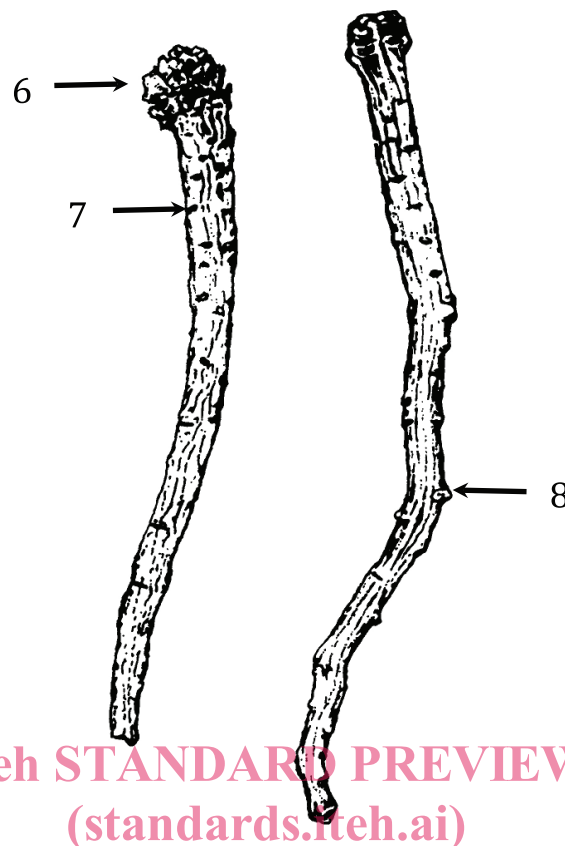
Note 1 to entry: Final samples may be packed in different materials meeting conditions for specific tests (e.g. moisture or total ash).

4 Descriptions

Isatis indigotica root is the dried root of *Isatis indigotica* Fort in the family of Brassicaceae as shown in [Figure 1](#).



a) Plant of *Isatis indigotica* Fort



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b) Dried root

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Key

1	flower	5	root
2	fruit	6	stem residue
3	stem	7	lenticel
4	leaf	8	rootlet scars

Figure 1 — Structure of *Isatis indigotica* Fort (a) and *Isatis indigotica* root (b)

5 Requirements

5.1 Morphological features

5.1.1 Appearance

The root is cylindrical and slightly twisted, with longitudinal wrinkles, transverse lenticels (7) and rootlets or rootlet scars (8) as shown in [Figure 1](#) b).

5.1.2 Colour

The external surface is pale grayish-yellow to brownish-yellow.

5.1.3 Dimension

The root is 10 cm to 20 cm in length measured from the base to the end of the root and 0,5 cm to 2 cm in diameter measured at the base of the root (1 cm from the position of stem residues).

5.1.4 Stem residue

The base slightly expanded, with dark green or dark brown threaded stem residue (6) as shown in [Figure 1 b](#)).

5.1.5 Texture

The texture is compact or slightly soft.

5.1.6 Fracture

The fracture is yellowish-white or yellowish-brown in cortex and yellow or brown in xylem.

5.1.7 Odour

The odour is slight, the taste is at first slightly sweet and then bitter and astringent.

5.2 Moisture

The moisture content in percentage mass should not be more than 15,0 %.

5.3 Total ash

The total ash content in percentage mass should not be more than 9,0 %.

5.4 Acid-insoluble ash

The total ash content in percentage mass should not be more than 2,0 %.

5.5 Ethanol-soluble extractives

The ethanol-soluble extracts content in percentage mass should not be less than 25,0 %.

5.6 Identification of marker compound

The identification of marker compound, such as (R,S)-goitrin with thin-layer chromatogram (TLC), shall present spots or brands obtained from the test and reference solutions in the same position with the same colour.

5.7 Content of marker compound

The contents of marker compound, such as (R,S)-goitrin, shall be determined.

5.8 Heavy metals

The contents of heavy metals, including arsenic, mercury, lead and cadmium, shall be determined.

5.9 Pesticide residues

The contents of pesticide residues, such as Benzex, DDT and quintozone, shall be determined.

6 Sampling

Sampling of *Isatis indigotica* root shall be in accordance with the World Health Organization's *Quality control methods for herbal materials: General advice on sampling*.

- a) From a batch of five containers or packaging units, take a sample from each one.
- b) From a batch of 6 to 50 units, take a sample from five.
- c) From a batch of over 50 units, sample 10 %, rounding up the number of units to the nearest multiple of 10. For example, a batch of 51 units would be sampled as for 60, i.e. take samples from six packages.
- d) From each container or package selected, take three original samples from the top, middle and bottom of the container or package. The three original samples should then be combined into a pooled sample that should be mixed carefully.
- e) The average sample is obtained by quartering. From the pooled sample, adequately mix into an even and square-shaped heap, and divide it diagonally into four equal parts. Take two diagonally opposite parts and mix carefully.
- f) Repeat the process as necessary until the required quantity, to within ± 10 %, is obtained.
- g) Using the same quartering procedure, divide the average sample into four final samples, taking care that each portion is representative of the bulk material.
- h) The final samples are tested for the measurement and analyses specified in [Table 1](#).

Table 1 — Maximum mass of batch and minimum mass of the final sample

Maximum mass of root per batch (kg)	Minimum mass of the final sample (g)		
	For macroscopic identification	For determination of marker compound	For other analyses
1 000	500	250	250

NOTE 1 The requirements are based on samples collected from different production regions of *Isatis indigotica* root.

NOTE 2 Other analyses include the determination of moisture content, total ash, acid-insoluble content, water- and ethanol-soluble extractives, heavy metals and pesticide residues.

7 Test methods

7.1 Macroscopic identification

Samples not less than 500 g are taken from each batch randomly. These samples are examined by the naked eye, smell and taste.

7.2 Determination of moisture content

The testing method specified in ISO 20409 applies.

7.3 Determination of total ash content

The testing method specified in ISO 1575 applies.

7.4 Determination of acid-insoluble ash content

The testing method specified in ISO 1577 applies.