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Traditional Chinese Medicine — *Scutellaria baicalensis* root

Médecine traditionnelle chinoise — Racine de Scutellaria baicalensis

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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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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

Scutellaria baicalensis is a traditional herbal medicine with the common name Baikal skullcap or Chinese skullcap. It is a species of flowering plant of the genus *Lamiaceae*, widely distributed in China, the Russian Federation, Mongolia and the Democratic People's Republic of Korea. It is one of the 50 fundamental herbs used in traditional Chinese medicine and is known as huángqín (黄芩) in Chinese. Its root is the main medicinal part.

As a traditional Chinese herbal medicine, *Scutellaria baicalensis* has shown significant effects in the treatment of various diseases and conditions, including insomnia, anxiety, stroke, fever, high cholesterol, atherosclerosis, rabies, epilepsy, nervous tension, allergies, skin infections, inflammation and spasms. It is also used for the treatment of hepatitis, atherosclerosis, hypertension, hyperlipidemia, type 2 diabetes, dysentery, ulcerative colitis and respiratory disorders.

The purpose of this document is to provide systematic and comprehensive methods for the quality control of *Scutellaria baicalensis* for direct medicinal and pharmaceutical use.

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 C](#).

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Traditional Chinese Medicine — *Scutellaria baicalensis* root

1 Scope

This document specifies minimum requirements and test methods for root of *Scutellaria baicalensis*, which is derived from cultivated *Scutellaria baicalensis* Georgi.

This document applies to *Scutellaria baicalensis* root that are sold and used as natural medicines 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 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, *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

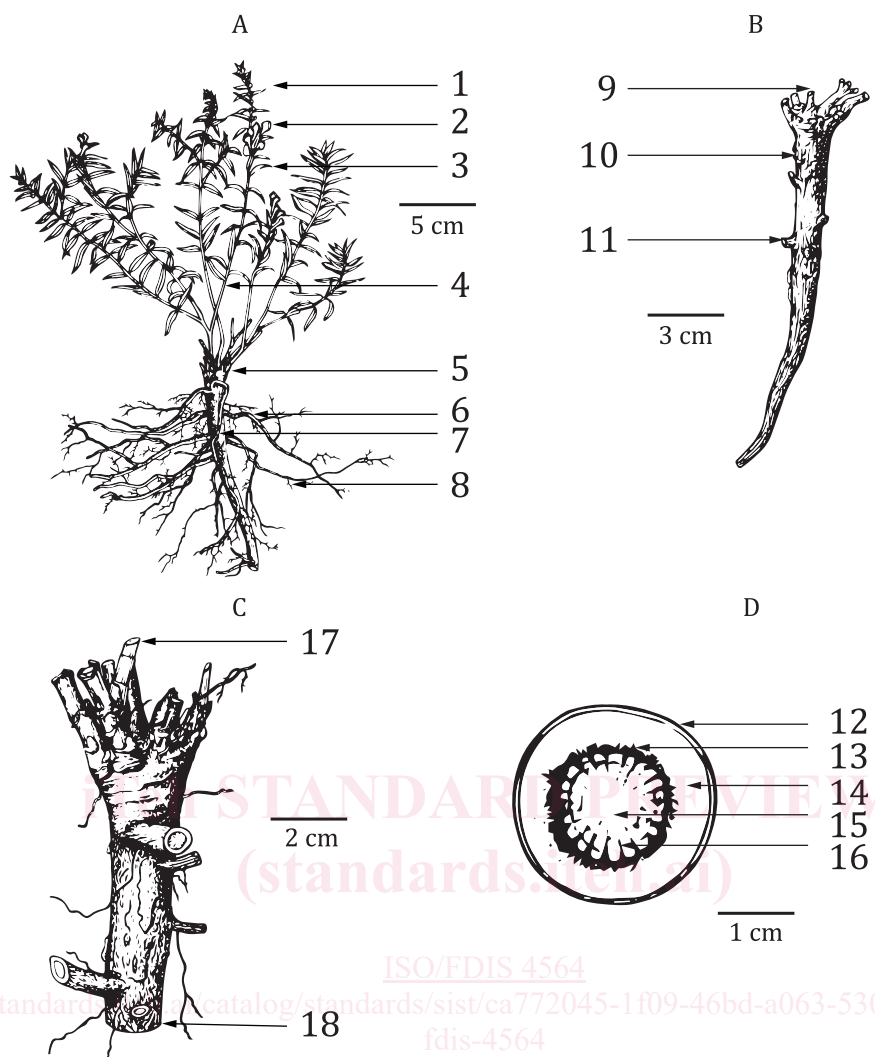
batch

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

[SOURCE: ISO 23972:2021,3.1]

4 Descriptions

The plant and dried *Scutellaria baicalensis* root are shown in [Figure 1](#).



Key

- | | | | |
|---|---|----|------------------------------------|
| A | plant of <i>Scutellaria baicalensis</i> | C | tap root without lateral root |
| B | dried tap root | D | transverse section of the tap root |
| 1 | flowering branch | 10 | warty protruding |
| 2 | flower | 11 | lateral root scar |
| 3 | leaf | 12 | epidermis |
| 4 | stem | 13 | vascular cambium |
| 5 | rhizome | 14 | phloem |
| 6 | lateral root | 15 | xylem |
| 7 | tap root | 16 | ray |
| 8 | rootlets | 17 | stem scar |
| 9 | stem scar | 18 | root scar |

Figure 1 — Structure of *Scutellaria baicalensis* root

5 Requirements

5.1 General characteristics

The following requirements shall be met before sampling.

- a) *Scutellaria baicalensis* root shall be clean and free from steam, leave and foreign matter.
- b) The presence of living insects, mouldy root and external contaminants which are visible to the naked eye shall not be permitted.

5.2 Morphological features

- a) The root is conical and twisted as shown in [Figure 1](#).
- b) The whole tap root is 8 cm to 25 cm long and 1 cm to 3 cm in diameter.
- c) The outer surface is brownish-yellow or dark yellow, bearing sparse, warty traces of rootlets. The upper part is rough, with twisted longitudinal wrinkles or irregular reticula; the lower part has longitudinal striations and fine wrinkles.
- d) The texture is hard, fragile and easily broken.
- e) The fracture is yellow, reddish-brown in the centre. The central part of an old root is dark brown or brownish-black, withered or hollowed.

5.3 Microscopic identification

5.3.1 Transverse section

- a) Cork consists of several layers of cells, mostly broken. The cortex is narrow, scattered with stone cells.
- b) The phloem is broad, scattered with single or groups of stone cells.
- c) The cambium is distinct. Xylem vessels occur singly or grouped, surrounded by xylem fibre bundles, with xylem rays relatively broad.
- d) Interxylary cork tissue is found in the xylem of roots of plants older than two years old, with several layers of well-ordered cork cells enclosing the vessels.
- e) Parenchyma cells are replete with starch granules.

5.3.2 Powder

- a) The colour of the powder is yellow.
- b) Phloem fibres is fusiform, scattered singly or in bundles. It is 60 µm to 250 µm long, 9 µm to 33 µm in diameter, and thick-walled, with fine pit-canals.
- c) Stone cells are suborbicular, subsquare or rectangular, relatively thick-walled or heavily thick-walled. Xylem fibres are mostly broken with sparse oblique pits.
- d) Cork cells are brownish-yellow, polygonal in surface view.
- e) Vessels are mainly reticulated, 24 µm to 72 µm in diameter.
- f) Starch granules are abundant. They are 2 µm to 10 µm. The simple granule is spheroidal and hilum is distinct. The compound granules are composed of 2-3 units.

5.4 Moisture

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

5.5 Total ash

The mass fraction of total ash should not be more than 6,0 %.

5.6 Ethanol-soluble extractives

The mass fraction of extractives should be determined.

5.7 Thin-layer chromatogram identification

The identification of baicalin with thin-layer chromatogram (TLC) shall present spots from the test and reference solutions in the same position with the same colour.

5.8 Content of marker compounds

The content of marker compound(s) such as baicalin, baicalein and wogonin shall be determined.

5.9 Heavy metals

The content of heavy metals such as arsenic, mercury, lead, cadmium shall be determined.

5.10 Pesticide residues

The content of pesticide residues shall be determined.

6 Sampling

The sampling method specified in ISO 23723 shall apply.

7 Test methods

7.1 Macroscopic identification

Take samples of not less than 500 g from each batch randomly. These samples shall be examined by naked eye observation in sunlight.

7.2 Microscopic identification

The testing method specified in ISO/TS 21310 shall apply.

7.3 Determination of moisture content

The testing method specified in ISO 23723 shall apply.

7.4 Determination of total ash content

The testing method specified in ISO 23723 shall apply.

7.5 Determination of ethanol-soluble extractives

The testing method specified in ISO 23723 shall apply.

7.6 Thin-layer chromatogram identification

See [Annex A](#) for additional information.

7.7 Determination of marker compound

See [Annex B](#) for additional information.

7.8 Determination of heavy metals contents

The testing method specified in ISO 18664 shall apply.

7.9 Determination of pesticide residues contents

The testing methods specified in ISO 22258 shall apply.

8 Test report

For each test method, the test report shall specify the following:

- a) all information necessary for the complete identification of the sample;
- b) a reference to this document, i.e. ISO 4564:2023;
- c) the sampling method used;
- d) the test method used;
- e) the test result(s) used;
- f) all operating details not specified in this document, or regarded as optional, together with details of any incidents which have possibly influenced the test result(s);
- g) the date of the test.

9 Packaging, storage and transportation

The packaging shall not transmit any odour or flavour to the product and shall not contain substances that can damage the product or constitute a health risk.

The storage condition specified in ISO 22217 shall apply.

The product shall be protected from light, moisture, pollution and entry of foreign substances during long-distance delivery.

10 Marking and labelling

The following items shall be marked or labelled on the package in accordance with the method specified in ISO 21371:

- a) the grade of the product;
- b) all quality features indicated in [Clause 5](#);
- c) the maximum weight of the batch and the samples;
- d) the country and province or state of origin of the products;
- e) the expiry date of the products;