
**Traditional Chinese medicine —
Scutellaria baicalensis root**

Médecine traditionnelle chinoise — Racine de Scutellaria baicalensis

STANDARDSISO.COM : Click to view the full PDF of ISO 4564:2023



STANDARDSISO.COM : Click to view the full PDF of ISO 4564:2023



COPYRIGHT PROTECTED DOCUMENT

© ISO 2023

All rights reserved. Unless otherwise specified, or required in the context of its implementation, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

Contents

Page

Foreword.....	iv
Introduction.....	v
1 Scope.....	1
2 Normative references.....	1
3 Terms and definitions.....	1
4 Descriptions.....	1
5 Requirements.....	2
5.1 General characteristics.....	2
5.2 Morphological features.....	3
5.3 Microscopic identification.....	3
5.3.1 Transverse section.....	3
5.3.2 Powder.....	3
5.4 Moisture.....	3
5.5 Total ash.....	3
5.6 Ethanol-soluble extractives.....	4
5.7 Thin-layer chromatogram identification.....	4
5.8 Content of marker compounds.....	4
5.9 Heavy metals.....	4
5.10 Pesticide residues.....	4
6 Sampling.....	4
7 Test methods.....	4
7.1 Macroscopic identification.....	4
7.2 Microscopic identification.....	4
7.3 Determination of moisture content.....	4
7.4 Determination of total ash content.....	4
7.5 Determination of ethanol-soluble extractives.....	4
7.6 Thin-layer chromatogram identification.....	4
7.7 Determination of marker compounds.....	4
7.8 Determination of heavy metals contents.....	5
7.9 Determination of pesticide residues contents.....	5
8 Test report.....	5
9 Packaging, storage and transportation.....	5
10 Marking and labelling.....	5
Annex A (informative) Thin-layer chromatogram identification.....	6
Annex B (informative) Determination of marker compounds.....	8
Annex C (informative) Referenced information of national and regional requirements on <i>Scutellaria baicalensis</i> root.....	10
Bibliography.....	12

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

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](#).

STANDARDSISO.COM : Click to view the full PDF of ISO 4564:2023

[STANDARDSISO.COM](https://standardsiso.com) : Click to view the full PDF of ISO 4564:2023

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

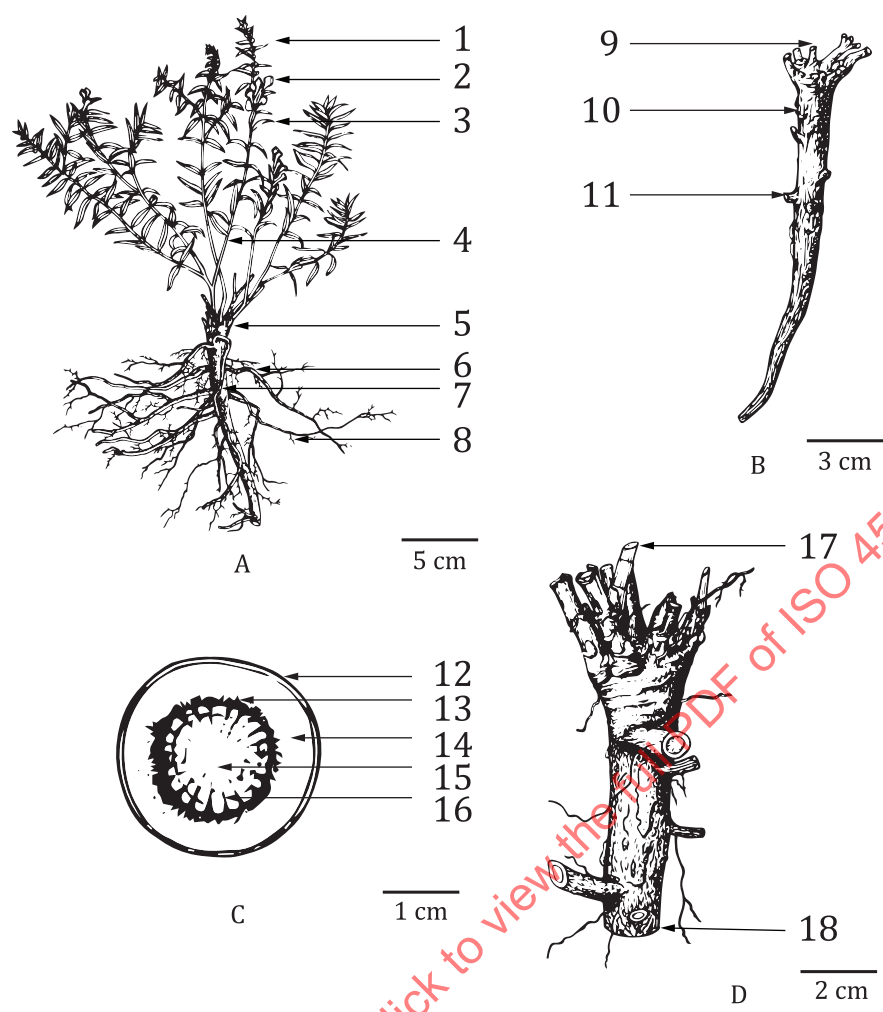
batch

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

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;
- f) the storage method used.

Annex A **(informative)**

Thin-layer chromatogram identification

A.1 Preparation of test solution

Weigh 250 g of sample to grind and pass it through an 80-mesh or finer sieve. Add 10 ml of methanol to 2 g of the powdered sample in a 100-ml round-bottomed flask, heat under reflux on a water bath for 3 min and filter.

A.2 Preparation of reference standard solution

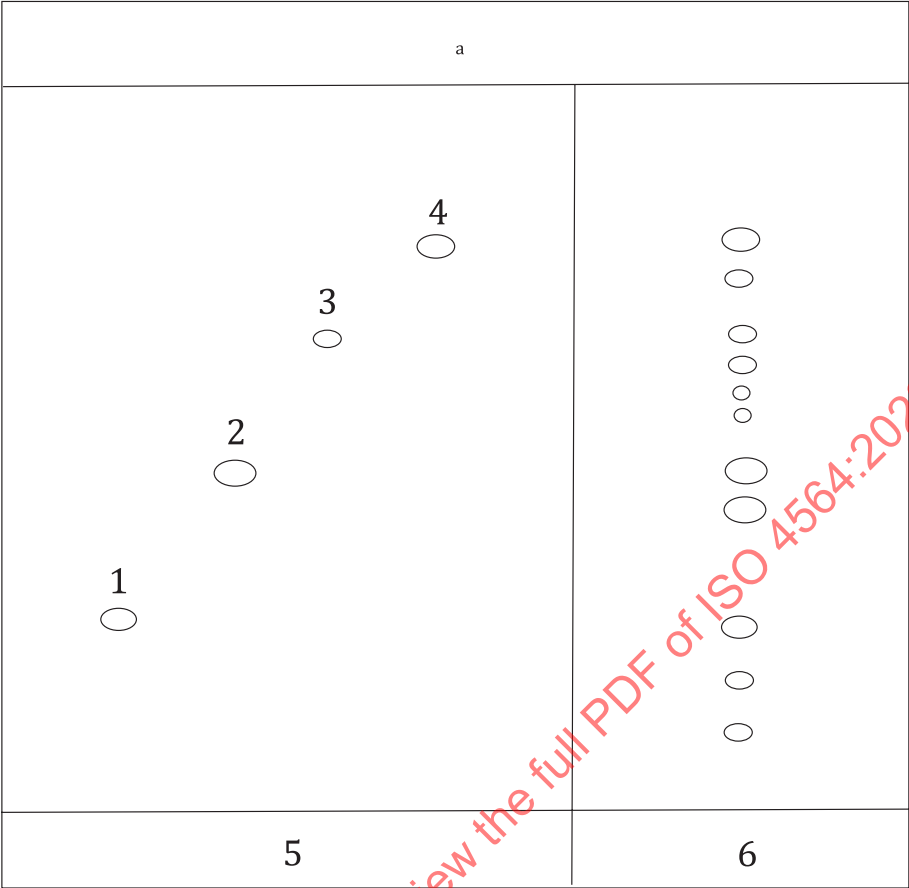
Dissolve baicalin, baicalein, wogonin and wogonoside in ethanol to prepare a mixed reference standard solution (CRS or adequate qualities) containing 1,0 mg/ml of baicalin, baicalein, wogonin and wogonoside.

A.3 Developing solvent system

Prepare a mixture of methyl benzene, ethyl acetate, methanol and formic acid in a volume ratio of 10:3:3:2 as the mobile phase.

A.4 Identification by TLC

Apply 2 µl of the test solution and 1 µl of the reference solution, respectively, to the F254 silica gel plate. Use the newly prepared developing solvent system as mentioned in [A.3](#) and pre-saturate the plate for 30 min. After spreading about 10 cm, dry the plate in air and examine under ultraviolet light (at 254 nm). Typical reference TLC chromatograms are shown in [Figure A.1](#).



- Key**
- 1 baicalin
 - 2 wogonoside
 - 3 baicalein
 - 4 wogonin
 - 5 reference solution
 - 6 test solution
 - a top of the plate

Figure A.1 — Schematic diagram of typical TLC chromatograms of *Scutellaria baicalensis* root

Annex B (informative)

Determination of marker compounds

B.1 Preparation of test solution

Weigh 250 g of sample to grind and pass it through an 80-mesh or finer sieve. Weigh accurately 0,3 g of the powdered sample, add 40 ml of 70 % ethanol, heat under reflux to slightly boil on a water bath for 3 h and cool. Filter to a 100-ml volumetric flask, rinse the container and residue three times with a tiny amount of 70 % ethanol and filter the washings to the volumetric flask. Dilute with 70 % ethanol to volume and mix. Accurately transfer 1 ml to a 10-ml volumetric flask, dilute with methanol to volume and mix.

B.2 Preparation of reference solution

Dissolve appropriate amount of reference substances baicalin, baicalein and wogonin into methanol to obtain the reference solution containing with concentrations shown in [Table B.1](#).

Table B.1 — Reference solution

Compound	Concentration
	mg/ml
Baicalin I ($C_{21}H_{18}O_{11}$)	0,66
Baicalein II ($C_{15}H_{10}O_5$)	0,016
Wogonin III ($C_{16}H_{12}O_5$)	0,008

B.3 Chromatographic conditions

B.3.1 Stationary phase: octadecylsilane bonded silica gel or equivalent as analysing column.

B.3.2 Size: $l = 150$ mm, $\varnothing = 4,6$ mm, particle size = $3,0$ μm .

B.3.3 Mobile phase:

B.3.3.1 Mobile phase A: 0,2 % phosphoric acid in methanol.

B.3.3.2 Mobile phase B: 0,2 % phosphoric acid in water.

B.3.3.3 Program of gradient elution as shown in [Table B.2](#).

B.3.4 Flow rate: 1,0 ml/min.

B.3.5 Detector 280 nm.

B.3.6 Injection volume: 10 μl .

B.3.7 Temperature of column oven: 30 °C.

Table B.2 — Typical chromatographic conditions

Time min	Mobile phase A volumic fraction in per cent	Mobile phase B volumic fraction in per cent
0 to 10	10 to 50	90 to 50
10 to 38	50 to 70	50 to 30
3 to 44	100	0

B.4 Content calculation of marker compounds

B.4.1 The percentage content of baicalin, W , is calculated using [Formula \(B.1\)](#):

$$W = \frac{C_s \times 10 \times 100}{m \times (1 - w_M)} \times 100 \tag{B.1}$$

where

- C_s is the average content in the sample (mg/ml);
- m is the mass of *Scutellaria baicalensis* root taken to prepare the sample solution (g);
- w_M is the moisture content of the sample (%).

B.4.2 A typical HPLC chromatogram is shown in [Figure B.1](#).

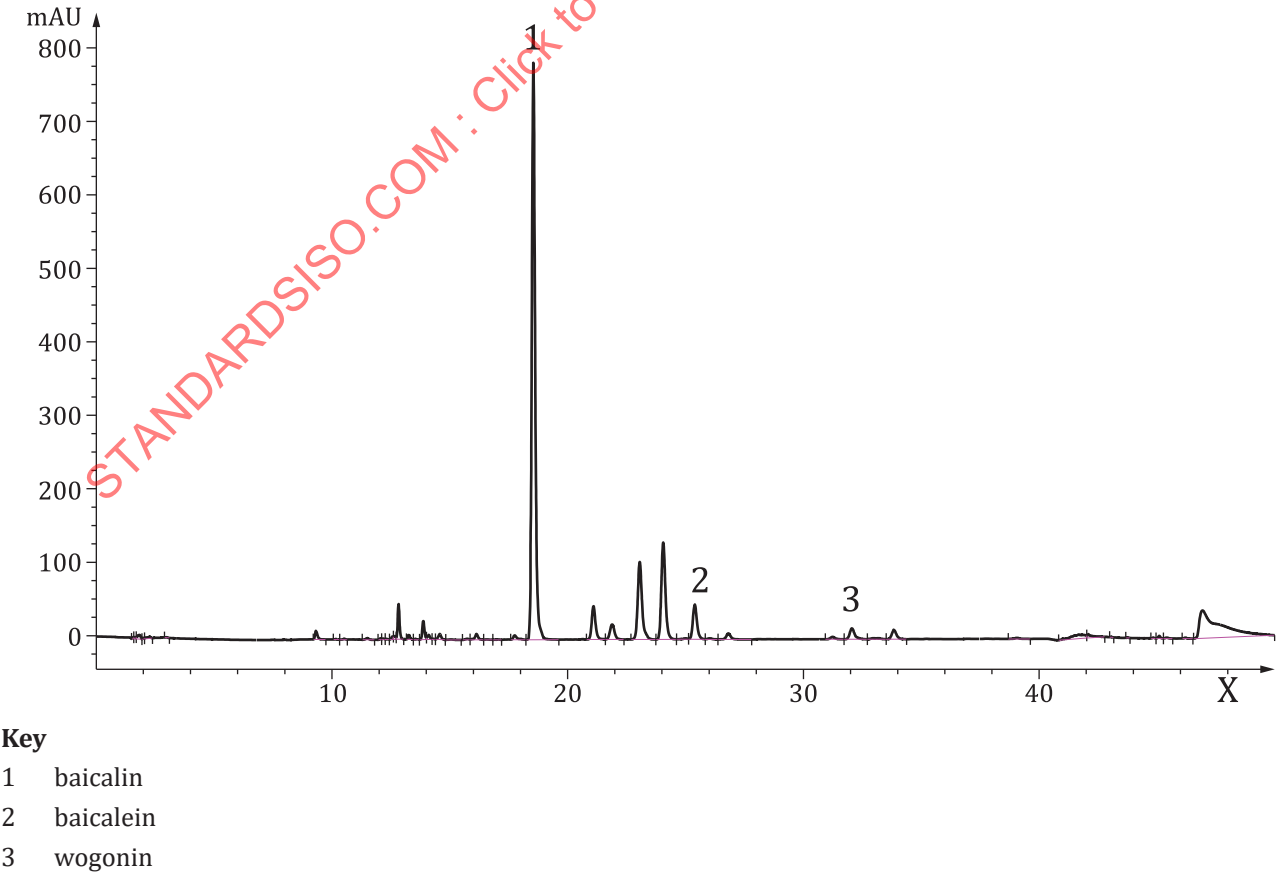


Figure B.1 — Typical HPLC chromatograms of *Scutellaria baicalensis* root

Annex C (informative)

Referenced information of national and regional requirements on *Scutellaria baicalensis* root

Different countries and regions give their own requirements on *Scutellaria baicalensis* root as shown in [Table C.1](#).

Table C.1 — National and regional quality requirements of *Scutellaria baicalensis* root

Item		Chinese Pharmacopoeia, 2020 Edition	European Pharmacopoeia, 10th Edition	Japanese Pharmacopoeia, 18th Edition	Korean Pharmacopoeia, 12th Edition	Chinese Hong Kong Chinese Material Medica Standards	Chinese Taiwan Herbal Pharmacopoeia, 3rd Edition
Plant origin		<i>Scutellaria baicalensis</i> Georgi	<i>Scutellaria baicalensis</i> Georgi	<i>Scutellaria baicalensis</i> Georgi	<i>Scutellaria baicalensis</i> Georgi	<i>Scutellaria baicalensis</i> Georgi	<i>Scutellaria baicalensis</i> Georgi
Medicinal part		Root	Root	Root	Root	Root	Root
Identification		Microscope, TLC	Microscope, TLC	Microscope, Chemical colour reaction, TLC	Chemical colour reaction, TLC	Microscope, TLC, HPLC	Microscope, TLC
Content	Baicalin	≥9,0 %	≥9,0 %	≥10,0 %	≥10,0 %	≥12,0 %	≥8,0 %
	Baicalein	—	—	—		—	—
	Wogonin	—	—	—		—	—
Moisture		≤12,0 %	—	—	—	≤11,0 %	—
Loss on drying		—	≤10,0 %	≤12,0 %	≤15,0 %	—	≤14,0 %
Foreign matter		—	—	—	—	—	—
Total ash		≤6,0 %	≤6,0 %	≤6,0 %	≤6,0 %	≤5,5 %	≤6,0 %
Acid-insoluble ash		—	≤2,0 %	—	≤1,0 %	≤1,5 %	≤2,0 %
Extractives	Water-soluble	—	—	—	—	≥30,0 %	≥18,0 %
	Ethanol-soluble extractives	≥40,0 %	—	—	—	≥46,0 %	≥26,0 %
Heavy metals	Lead	—	—	≤10,0 ppm	≤5,0 ppm	≤5,0 mg/kg	≤5,0 ppm
	Arsenic	—	—	≤5,0 ppm	≤3,0 ppm	≤2,0 mg/kg	≤5,0 ppm
	Mercury	—	—	—	≤0,2 ppm	≤0,2 mg/kg	≤0,2 ppm
	Cadmium	—	—	—	≤0,3 ppm	≤1,0 mg/kg	≤1,0 ppm
	Total DDT			—	≤0,1 ppm	≤1,0 mg/kg	—
	Dieldrin			—	≤0,01 ppm	—	—
	Toral BHC			—	≤0,2 ppm	—	—
	Aldrin			—	≤0,01 ppm	—	—
Key							
— Not applicable							