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Traditional Chinese medicine — *Cinnamomum cassia* branch

Médecine traditionnelle chinoise — Branche de Cinnamomum cassia

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Foreword

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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

Cinnamomum cassia branch, the dried young branch of *Cinnamomum cassia* Presl (Lauraceae), has been used as a medicinal herb worldwide for a long time. According to traditional Chinese medicine (TCM) theory, it has various therapeutic effects, including dissipating cold and releasing the exterior, warming and unblocking meridians, assisting yang and transforming into qi. Clinically, *Cinnamomum cassia* branch is used to treat wind-cold common cold, cold-induced stomach duct and abdominal pain, arthralgia, phlegm-fluid retention, oedema, palpitations, running piglet, etc.

There is a large market demand for *Cinnamomum cassia* branch due to its frequent use in clinical prescriptions and compound preparations of TCM. However, cinnamaldehyde, one of the active ingredients of *Cinnamomum cassia* branch, becomes unstable when stored improperly and can lead to reduced efficacy. Moreover, the international trade of *Cinnamomum cassia* branch faces challenges due to varying in quality standards across different countries or regions.

To ensure the quality and enhance the market value of *Cinnamomum cassia* branch, the establishment of an International Standard is crucial. This document can help guarantee quality and clinical effectiveness, promote standardization and modernization, and regulate production, trade and usage. This document includes the following requirements for *Cinnamomum cassia* branch: macroscopic morphological observation, microscopic characteristics of transverse section and powder, phytochemical indexes, and standardized physical and chemical tests (moisture, total ash, and ethanol-extractives content). Volatile oils are the main active ingredient in Lauraceae plants. Among them, cinnamaldehyde, which has specific pharmacological activities such as anti-inflammation, anti-oxidation and anti-myocardial ischemia, is closely related to the biological activity of *Cinnamomum cassia* branch. In this document, a thin-layer chromatography (TLC) identification method using *Cinnamomum cassia* branch reference as a marker is established. Additionally, a high-performance liquid chromatography (HPLC) analysis method of *Cinnamomum cassia* branch using cinnamaldehyde as a marker is also developed.

As national implementation can differ, national standards bodies are invited to modify the values given in 5.5 and 5.6 in their national standards. An example of national values is given in Annex D.

Traditional Chinese medicine — *Cinnamomum cassia* branch

1 Scope

This document specifies the quality and safety requirements for *Cinnamomum cassia* branch derived from *Cinnamomum cassia* Presl.

This document is applicable to *Cinnamomum cassia* branch that is sold as natural medicines in international trade including Chinese materia medica (whole medicinal materials) and decoction pieces derived from *Cinnamomum cassia* Presl.

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

ISO 22258, *Traditional Chinese medicine — Determination of pesticide residues in natural products by gas chromatography*

ISO 22590, *Traditional Chinese medicine — Determination of sulfur dioxide in natural products by titration*

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
***Cinnamomum cassia* branch**
dried young branch of *Cinnamomum cassia* Presl. (Fam. Lauraceae)

3.2
marker compound
chemical constituent within a medicinal herb that can be used to verify its quality

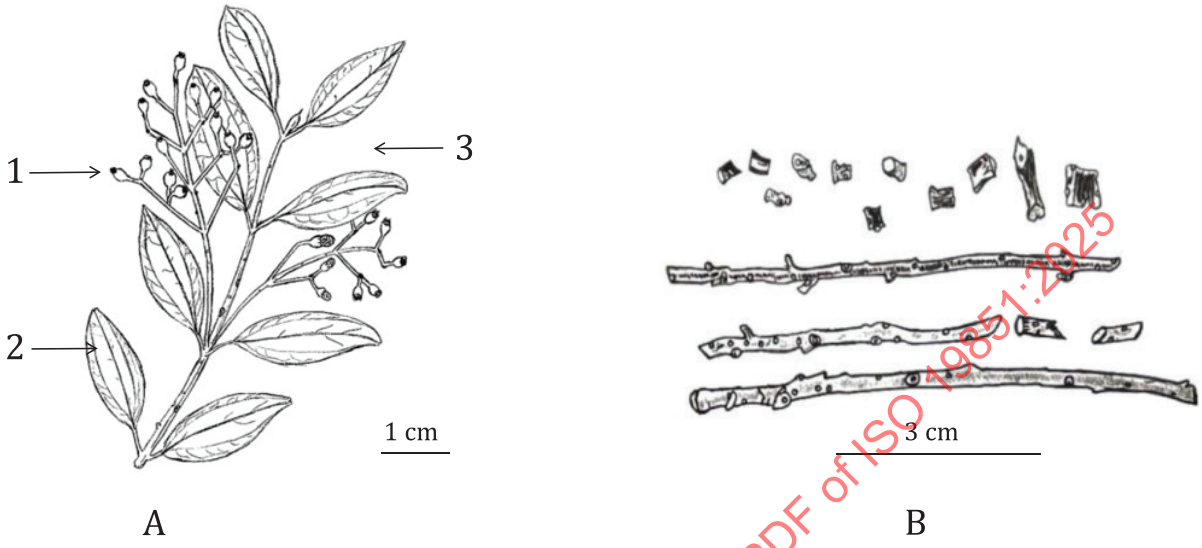
Note 1 to entry: Usually described as active ingredients or chemicals that confirm the correct botanical identity of the starting material.

Note 2 to entry: There may be one or more marker compounds for a medicinal herb.

[SOURCE: ISO 22585:2022, 3.2]

4 Descriptions

Cinnamomum cassia branch is the dried young branch of *Cinnamomum cassia* Presl, as shown in Figure 1. The young branch is collected in spring and summer, with the leaves removed, and then dried in the sun, or dried in the sun after sliced. As *Cinnamomum burmanni* branch is a similar species of *Cinnamomum cassia* branch, a method for differentiating these two species is given in Annex C.



Key

A *Cinnamomum cassia* Presl.
B dried young branch
1 fruit
2 leaf
3 branch

Figure 1 — Structure of *Cinnamomum cassia* Presl. (Lauraceae)

5 Quality and safety requirements and recommendations

5.1 General requirements

The following requirements shall be met before sampling.

a) *Cinnamomum cassia* branch shall be clean and free from leaves and foreign matter.

b) The presence of living insects, mouldy branch and external contaminants which are visible to the naked eye shall not be permitted.

5.2 Morphological features

a) The branches are long and cylindrical, with multiple branches, 30 cm to 75 cm long, 0,3 cm to 1 cm in diameter at the thicker end.

b) The external surface is reddish-brown to brown, with longitudinal ridges, fine wrinkles, dotted lenticels, pimple-like leaf scars, branch scars and bud scars. The texture is hard and fragile, easily broken.

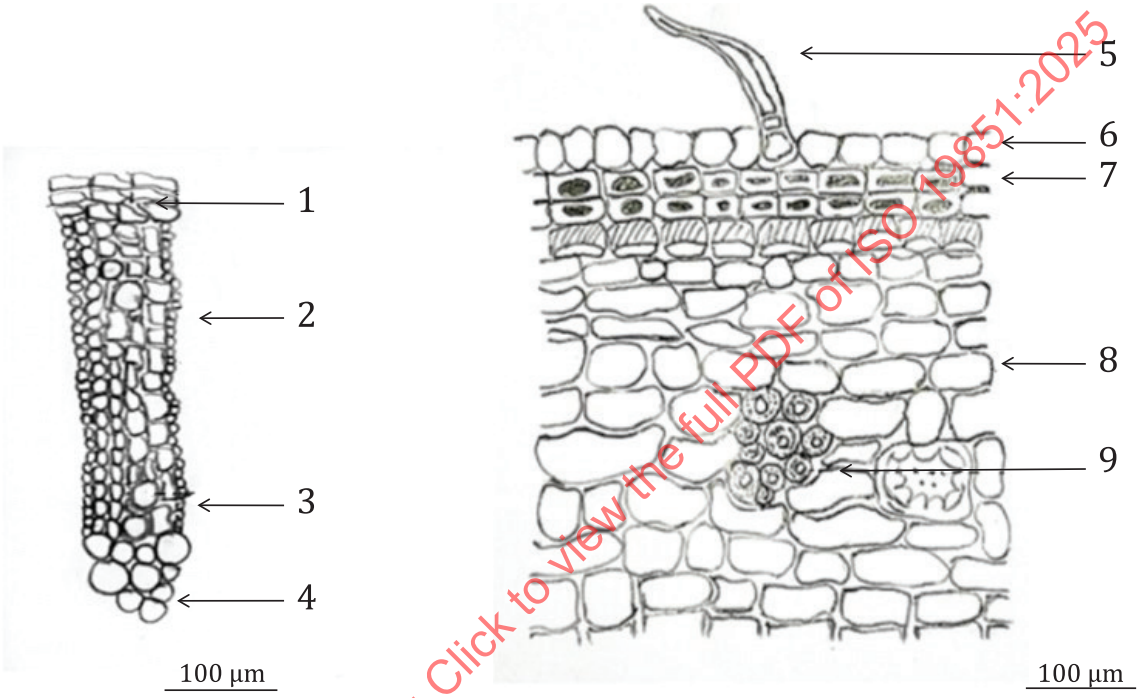
c) The slice thickness is 2 mm to 4 mm. On the cut surface, the bark is reddish-brown; the wood is yellowish-white to light yellowish-brown, and the pith is slightly square.

d) This product has a special aroma, with a sweet and slightly pungent taste. The bark has a strong flavour.

5.3 Microscopic features

5.3.1 Transverse section

The epidermis consists of a single layer of cells, and unicellular nonglandular hairs are sometimes visible in young branches. The cork layer comprises 3 to 5 layers of cells, with the outer walls of cells in the innermost layer being thickened. Oil cells and stone cells are scattered in the cortex. Groups of stone cells in the pericycle are intermittently arranged in rings, accompanied by fibre bundles. The phloem contains scattered secretory cells and fibres. The cambium is distinct. The xylem rays are 1 to 2 cells wide and contain brown substances; vessels are scattered singly or 2 to several aggregated; the walls of wood fibres are thin and indistinguishable from xylem parenchyma cells. In the pith, cell walls are slightly thickened and lignified. Small calcium oxalate needle crystals are occasionally observed in ray cells (see Figure 2).



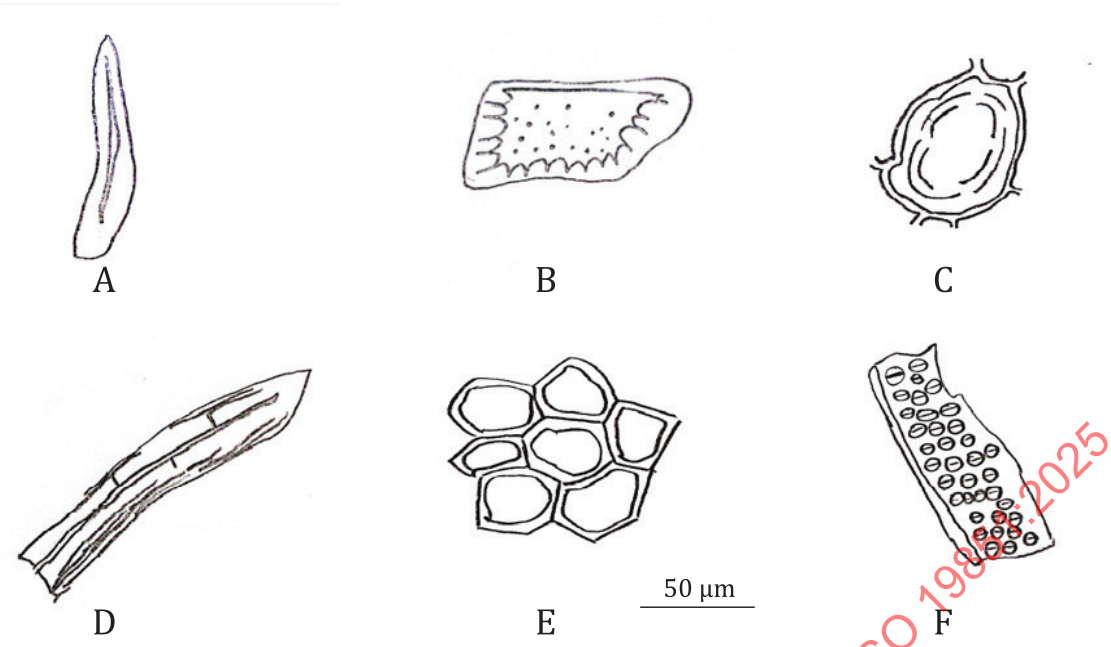
Key

1	cambium	5	nonglandular-hair
2	ray	6	epidermis
3	vessel	7	cork layer
4	medulla	8	cortex
		9	fibre bundle

Figure 2 — Microscopic features of transverse section of *Cinnamomum cassia* Presl. (Lauraceae)

5.3.2 Powder

The powder is reddish-brown. The stone cells are subsquare or subrounded, 30 µm to 64 µm in diameter; the walls are thick, although some walls are thin on one side. The phloem fibres are mostly fascicular or scattered singly, colourless or brown, fusiform, with some edge being dentate protruding, 12 µm to 40 µm in diameter, with very thick and lignified walls, and inconspicuous pores and furrows. The oil cells are subround or elliptic, 41 µm to 104 µm in diameter. The wood fibres are numerous and often appear in bundles, with twill holes or intersecting into a cross. The cork cells are yellowish-brown, polygonal in surface view, and contain reddish brown matter. The vessels are mainly with bordered pits and up to 76 µm in diameter (see Figure 3).



Key

A	phloem fibre	B	stone cell
C	oil cell	D	wood fibre
E	cork cell	F	vessel

Figure 3 — Microscopic features of the powder of *Cinnamomum cassia* Presl. (Lauraceae)

5.4 Thin-layer chromatogram identification

When thin-layer chromatogram identification (TLC) is performed, the TLC shall present the spots specific to *Cinnamomum cassia* branch.

5.5 Moisture

The mass fraction of moisture should not be more than 15,0 %.

5.6 Total ash

The mass fraction of total ash should not be more than 4,0 %.

5.7 Ethanol-soluble extractives

The mass fraction of ethanol-soluble extracts should be determined.

5.8 Marker compounds

The mass fractions of marker compounds, such as cinnamaldehyde, should be determined.

5.9 Heavy metals

The mass fractions of heavy metals, such as arsenic, mercury, lead and cadmium, should be determined.

5.10 Pesticide residues

The mass fractions of pesticide residues, such as hexachlorocyclohexane, dichlorodiphenyltrichloroethane (DDT) and pentachloronitrobenzene, shall be determined.

5.11 Sulfur dioxide residues

The mass fractions of sulfur dioxide residues should be determined.

6 Sampling

Sampling of *Cinnamomum cassia* branch shall be carried out in accordance with the method specified in ISO 23723.

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, smelled and tasted.

7.2 Determination of moisture

The test method specified in ISO 23723 shall apply.

7.3 Determination of total ash

The test method specified in ISO 23723 shall apply.

7.4 Determination of ethanol-extractives

The test method specified in ISO 23723 shall apply.

7.5 Thin-layer chromatogram identification

See Annex A for additional information.

7.6 Determination of marker compound (cinnamaldehyde)

See Annex B for additional information.

7.7 Determination of heavy metals

The test method specified in ISO 18664 shall apply.

7.8 Determination of pesticide residues

The test method specified in ISO 22258 shall apply.

7.9 Determination of sulfur dioxide residues

The test method specified in ISO 22590 shall apply.

8 Test report

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

a) all the information necessary for the complete identification of the sample;

b) the sampling method used;

c) the test method used, with reference to this document;

d) the test result(s) obtained;

e) all operating details not specified in this document, or regarded as optional, together with details of any incidents which can have influenced the test result(s);

f) any unusual features (anomalies) observed during the test;

g) the date of the test.

9 Packaging, storage and transportation

Packaging shall not transmit any odour or flavour to the product and shall not contain substances which can damage the product or constitute a health risk. The packaging and transportation requirements specified in ISO 23723 shall apply. The storage requirements specified in ISO 22217 shall apply.

The product drug shall be sealed and stored in a dry, shady and cool place.

The products 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 packages in accordance with the method specified in ISO 21371:

a) product name;

b) category of the product in the marketed country or region;

c) net mass or quantity;

d) contact information;

e) name of raw materials;

f) warning statements, if any;

g) expiry date;

h) storage method;

i) batch or lot number;

j) miscellaneous.

Annex A
(informative)

Thin-layer chromatogram identification of *Cinnamomum cassia* branch

A.1 Preparation of test solution

Weigh 250 g of the *Cinnamomum cassia* branch sample to grind and pass it through an 80-mesh or finer sieve. Weigh 2 g of the powder, add 10 ml of ether, soak for 30 min, shake constantly, filter, and dry the filtrate. Dissolve the residue by adding 1 ml trichloromethane to prepare the test solution.

A.2 Preparation of reference solution

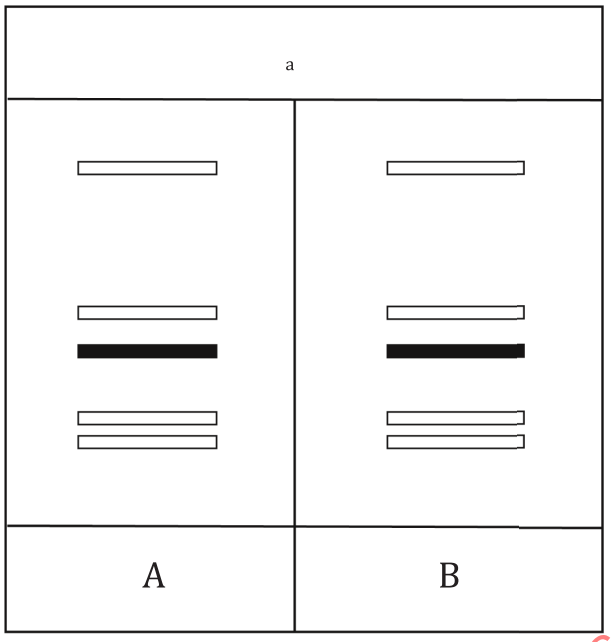
Take 2 g of the *Cinnamomum cassia* branch reference drug, and prepare the reference solution following the method described in A.1.

A.3 Developing solvent system

Prepare a mixture of petroleum ether (60 °C to 90 °C) and ethyl acetate (17:3) as the mobile phase before use.

A.4 Procedure

Apply 5 µl to 15 µl of the reference solution and the test solution on the same TLC plate (silica gel G). Develop the plate in the above mobile phase, then remove it and dry in air. Spray the plate with vanillin sulfuric acid reagent, heat at 105 °C until spots or bands appear clearly. Identify the spots or bands of the test solution by comparing the positions and colours with the reference solution. Typical reference TLC chromatograms are shown in Figure A.1.



Key

A reference solution

B test solution

[a] Top of the plate.

Figure A.1 — Schematic diagram of typical TLC chromatograms of *Cinnamomum cassia* branch

Annex B
(informative)

Determination of cinnamaldehyde content

B.1 Chromatographic conditions and system applicability

Octadecylsilane bonded silica gel or equivalent is used as the stationary phase. The mobile phase is acetonitrile-water (32:68). The detection wavelength is 290 nm. The theoretical plate number calculated according to the cinnamaldehyde peak should not be less than 3 000.

B.2 Preparation of reference solution

Dissolve a quantity of cinnamaldehyde reference standard in mobile phase to prepare a solution containing 10 µg per ml as the reference solution.

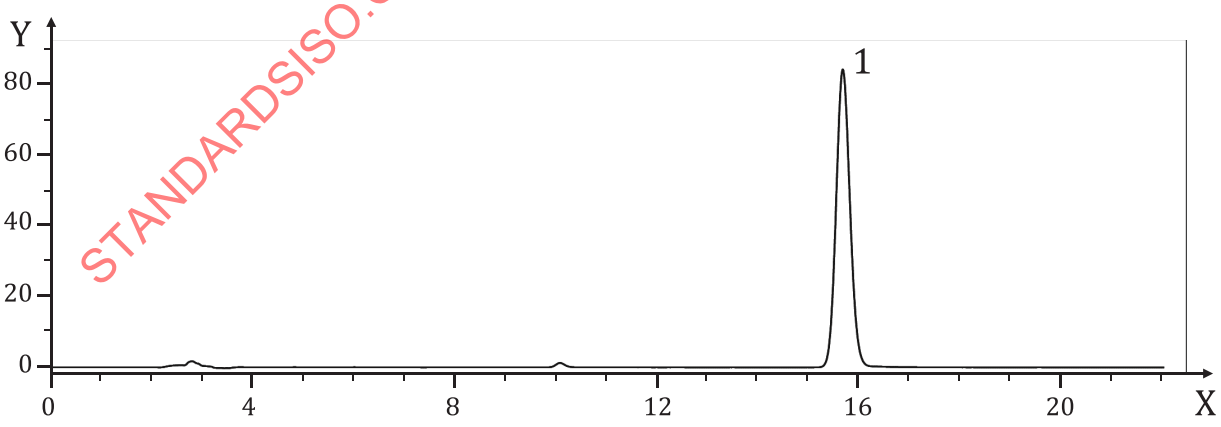
B.3 Preparation of test solution

Weigh 0,5 g of the powdered *Cinnamomum cassia* branch sample (through no. 4 sieve). Add 25 ml of methanol, stopper well and weigh. Ultrasonicate for 30 min (power 250 W, frequency 40 kHz), cool, weigh again and compensate the loss of the mass with methanol. Shake thoroughly, filter and transfer 1 ml of the successive filtrate to a 25 ml volumetric flask, dilute with methanol to volume, and shake thoroughly to prepare the test solution.

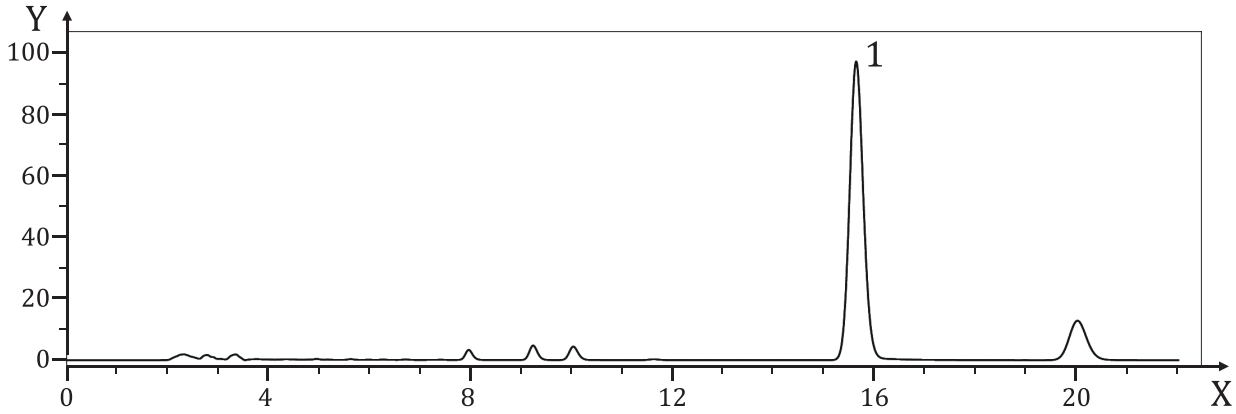
B.4 Determination

Inject 10 µl of the reference solution and the test solution respectively into the HPLC system, determine and record the chromatograms. The content of cinnamaldehyde should not be less than 0,5 % (the mass fraction) of the dried *Cinnamomum cassia* branch.

A typical reference HPLC chromatogram is shown in Figure B.1.



A



B

Key

X min
Y mAU
A HPLC chromatogram of cinnamaldehyde reference standard
B HPLC chromatogram of *Cinnamomum cassia* branch
1 cinnamaldehyde

Figure B.1 — Typical reference HPLC chromatograms of cinnamaldehyde content determination in *Cinnamomum cassia* branch

Annex C
(informative)

Reference information and method for differentiating *Cinnamomum cassia* and *Cinnamomum burmanni* branch

C.1 Preparation of test solution

Weigh 250 g of *Cinnamomum cassia* branch sample to grind and pass it through an 80-mesh or finer sieve. Weigh 2 g of the powder, add 10 ml of methanol and sonicate for 10 min. Centrifuge or filter, and transfer the extract to a round-bottom flask. Evaporate the solution under reduced pressure to dryness. Dissolve the residue in 2 ml of toluene, sonicate for about 2 min, centrifuge or filter, and use the supernatant or filtrate as the test solution.

C.2 Preparation of reference solutions

a) Take a certain amount of cinnamaldehyde reference standard and cinnamic acid reference standard, respectively, and add ethanol to prepare a solution containing 0,5 mg of cinnamaldehyde and 0,5 mg of cinnamic acid reference per ml as the reference solution.

b) Take 2 g of *Cinnamomum cassia* branch reference drug and prepare the *Cinnamomum cassia* branch reference drug solution following the method described in C.1.

c) Take 2 g of *Cinnamomum burmanni* branch and prepare the *Cinnamomum burmanni* branch solution following the method described in C.1.

C.3 Developing solvent system

Prepare a mixture of toluene and ethyl acetate (19:1) as the mobile phase before use.

C.4 Procedure

Apply 5 µl of the reference solution, the *Cinnamomum cassia* branch reference drug solution, the test solution and the *Cinnamomum burmanni* branch solution on the same TLC plate (chromatographic silica gel F_{254} mixture with an average particle size of about 5 µm). Develop in a saturated chamber (20 min with filter paper), remove the plate from the chamber, and dry in air. Examine under UV light at 254 nm. Identify the spots or bands of the test solution by comparing the positions and colours with the reference solution. Typical reference TLC chromatograms are shown in Figure C.1. This method can be used to differentiate *Cinnamomum cassia* branch from *Cinnamomum burmanni* branch, which lacks spot or band of cinnamic acid.