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**Traditional Chinese medicine —
Bupleurum chinense, *Bupleurum
scorzonerifolium* and *Bupleurum
falcatum* root**

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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.

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ISO/FDIS 23965

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

Bupleurum chinense, *Bupleurum scorzonerifolium* and *Bupleurum falcatum* root, namely Bupleuri Radix, are well-known traditional Chinese materia medica which have liver-protection, antipyretic and anti-inflammatory qualities. Bupleuri Radix is sold in many countries as medicinal materials or decoction pieces. Bupleuri Radix originates from cross-pollinating plants, which can easily lead to a hybrid of their provenance, in turn resulting in mixed sources of herbs. This can lead to difficulties in herb authenticity, as well as variations in herb efficacy and safety. Bupleuri Radix is included in several pharmacopeia, but with different plant origins. Thus, there is a need to standardize the quality to bring benefits to consumers and the enterprises involved in the processing, management and trade of *Bupleurum chinense*, *Bupleurum scorzonerifolium* and *Bupleurum falcatum* root.

As national implementation can differ, national standards bodies can modify the values given in [5.3](#), [5.4](#), [5.5](#), and [5.8](#) in their national standards. Examples of national and regional values are given in [Annex G](#).

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Traditional Chinese medicine — *Bupleurum chinense*, *Bupleurum scorzonerifolium* and *Bupleurum falcatum* root

1 Scope

This document specifies minimum requirements and test methods for *Bupleurum chinense*, *Bupleurum scorzonerifolium* and *Bupleurum falcatum* root.

This document applies to *Bupleurum chinense*, *Bupleurum scorzonerifolium* and *Bupleurum falcatum* root that are sold and used as natural medicines in international trade, including Chinese materia medica (whole medicinal materials) and decoction pieces.

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* <https://standards.iteh.ai/catalog/standards/sist/ecebdd28-237d-48d5-aa1b-c5a11f2d61ed/iso-fdis-23965>

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

root mass

average mass of final samples of root

Note 1 to entry: Root mass is measured in grams.

3.2

root length

largest distance from the bottom of the tap root to the stem scar

Note 1 to entry: Root length is measured in centimetres.

3.3

batch

samples collected from the same particular place at the same time

3.4

sample

representative material taken from a product, or part of a product

[SOURCE: ISO 11596:2008, 2.14, modified]

3.5

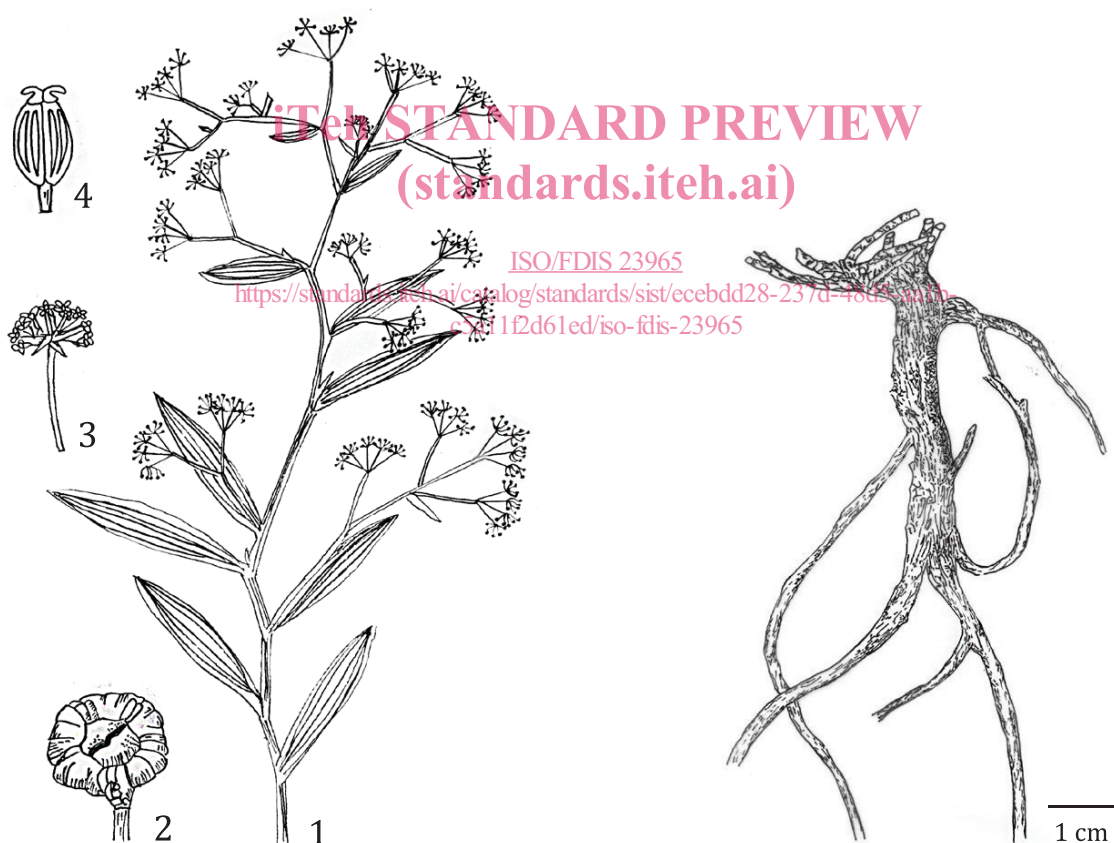
final sample

sample for the test required in this document

[SOURCE: ISO 21316:2019, 3.3, modified — Note to entry removed.]

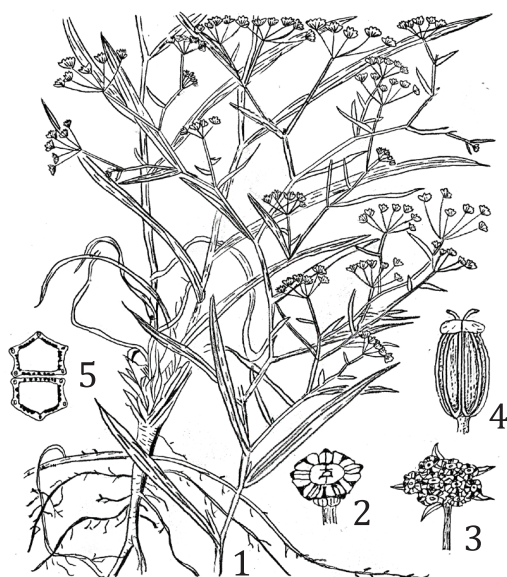
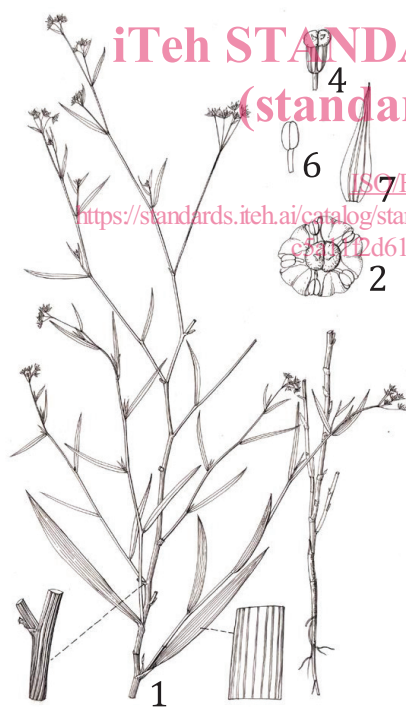
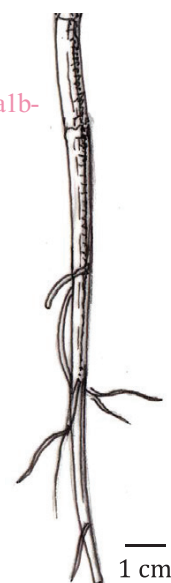
4 Description

The structures of *Bupleurum chinense* DC., *Bupleurum scorzonerifolium* Willd., *Bupleurum falcatum* L. and the dried root are shown in [Figure 1](#).



a) Plant of *Bupleurum chinense* DC.

b) *Bupleurum chinense* root

c) Plant of *Bupleurum scorzonerifolium* Willd.d) *Bupleurum scorzonerifolium* roote) Plant of *Bupleurum falcatum* L.f) *Bupleurum falcatum* root**Key**

- 1 flowering branch
- 2 flower
- 3 inflorescence
- 4 fruit

- 5 cross-section of fruit
- 6 stamen
- 7 sepal

Figure 1 — Structures of *Bupleurum chinense*, *Bupleurum scorzonerifolium* and *Bupleurum falcatum* root

5 Requirements

5.1 General characteristics

The following requirements shall be met before sampling:

- a) *Bupleurum chinense*, *Bupleurum scorzonrifolium* and *Bupleurum falcatum* root materials shall be clean and dry.
- b) The presence of living insects, mouldy root and external contaminants which are visible to the naked eye shall not be permitted.
- c) The shape of the root shall be cylindrical or long and conical.
- d) The root mass and the number of the residues shall be measured by electronic balance and counting.
- e) The outer surface shall be light brown with intermittent longitudinal wrinkles.

5.2 Macroscopic characteristics

5.2.1 *Bupleurum chinense*

The whole root is cylindrical or elongated conical, branched in the lower part, 6 cm to 15 cm in length and 0,3 cm to 0,8 cm in diameter. The upper part consists of a bulgy root crown, usually composed of 3 to 15 stem bases as well as the fibrous remnants of the leaf bases. The outer surface is blackish-brown or light brown, marked with longitudinal wrinkles and showing rootlet scars and lenticel-like protuberances. The texture is hard and compact, and difficult to break. The fracture shows concentric fibrous rings in the wood; the bark is thin, light brown or orange-brown, while the wood is whitish-yellow.

5.2.2 *Bupleurum scorzonrifolium*

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The whole root is thinner than that of *Bupleurum chinense*, elongated conical, usually unbranched or very slightly branched in the lower part, up to 15 cm long and 0,3 cm to 0,5 cm in diameter. The root crown bears numerous fibres from the bases of wilted leaves in a brush-like shape. The outer surface is blackish-brown or reddish-brown and shows numerous annular striations near the root crown. The texture is slightly soft and the root breaks easily. The fracture is even and non-fibrous.

5.2.3 *Bupleurum falcatum*

The whole root is a long conical or column shape, single or branched, 10 cm to 15 cm in length and 0,5 cm to 1,5 cm in diameter. The upper part is thick and the lower part thin. The apex has numerous hairy fibres from withered leaves. The external surface is pale brown to brown with deep wrinkles. The texture is easily broken and the fractured surface is somewhat fibrous.

5.3 Moisture

The mass fraction of moisture should not be more than 10,0 %.

5.4 Total ash

The mass fraction of ash should not be more than 9,0 %.

5.5 Acid-insoluble ash

The mass fraction of acid insoluble ash should not be more than 3,5 %.

5.6 Thin-layer chromatogram (TLC) identification

The identification of marker compound, such as saikosaponin a, with TLC shall present the spots or bands obtained from the test and reference drug solution in the same position with the same colour.

5.7 Toxic adulterants of *Bupleurum longiradiatum* root

The characteristic fingerprint for the toxic adulterants of *Bupleurum longiradiatum* root should be determined.

5.8 Ethanol-soluble extractives

The mass fraction of ethanol-soluble extracts should not be less than 11,0 %.

5.9 Content of marker compounds

The content of marker compounds such as saikosaponin a and d shall be determined.

5.10 Heavy metals

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

5.11 Pesticide residues

The content of pesticide residues such as benzene hexachloride, DDT and pentachloronitrobenzene shall be determined.

5.12 Sulfur dioxide residues

The content of sulfur dioxide residues should be determined.

6 Sampling

Sampling of *Bupleurum chinense*, *Bupleurum scorzonnerifolium* and *Bupleurum falcatum* root shall be carried out in accordance with ISO 23723.

7 Test methods

7.1 Macroscopic identification

Samples of not less than 500 g are taken from each batch randomly and observed with the naked eye, smelled and tasted.

7.2 Determination of moisture content

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

7.3 Determination of total ash and acid-insoluble ash content

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

7.4 Determination of ethanol-soluble extractives content

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