
**Traditional Chinese medicine —
Panax notoginseng root and rhizome**

*Médecine traditionnelle chinoise — Rhizome et racine de Panax
notoginseng*

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Foreword

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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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For an explanation on 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 the following URL: www.iso.org/iso/foreword.html.

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Introduction

Panax notoginseng root and rhizome are medicinal parts of *Panax notoginseng* (Burk.) F.H. Chen named *Sanqi*, which is a well-known traditional Chinese medicine. Due to its ability to treat bleeding, blood stasis and some other blood disorders, *Panax notoginseng* root and rhizome soared to great importance during Qing dynasty times after being praised by the master herbalist Li Shizhen in the 16th century. *Panax notoginseng* root and rhizome are native to the southern Chinese provinces of Yunnan and Guangxi, as well as Vietnam. The root and rhizome exhibit a variety of botanical and biochemical similarities to ginseng, and are frequently consumed as soup. Despite this high rate of consumption, there are relatively few reported side effects, making *Panax notoginseng* root and rhizome two of the safest substances in traditional Chinese medicine. While most often consumed as a popular food tonic, practitioners of Oriental medicine know *Panax notoginseng* root and rhizome best for the medicinal qualities: moving stagnant blood, stopping bleeding and resolving swelling. Due to the high price and demand in the global market, trade in *Panax notoginseng* root and rhizome has been complicated by substitution, adulteration and species identification issues. The genuine material is often replaced by less valuable material(s), some of which exhibit potentially toxic properties. Therefore, the establishment of an international standard for *Panax notoginseng* root and rhizome is necessary to support the clinical effectiveness, safety and consistency of this valuable medicine in international trade.

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Traditional Chinese medicine — *Panax notoginseng* root and rhizome

1 Scope

This document specifies minimum requirements and test methods for notoginseng root and rhizome which are derived from the plant *Panax notoginseng* (Burk.) F.H. Chen.

It is applicable to notoginseng root and rhizome that are sold and used as food supplements, functional food or 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 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*

CODEX STAN 229-1993, REV1-2003: *Analysis of pesticide residues: Recommended methods*

CODEX STAN 1-1985: *Codex general standard for the labelling of prepackaged foods*

CAC/MRL01-2009: *Maximum Residue Limits for Pesticides in Foods*

World Health Organization 2011: *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:

- IEC Electropedia: available at <http://www.electropedia.org/>
- ISO Online browsing platform: available at <http://www.iso.org/obp>

3.1

notoginseng

plant of *Panax notoginseng* (Burk.) F. H. Chen that has been cultivated for at least three years

3.2

root weight

average weight of final samples of root

3.3

root length

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

Note 1 to entry: See [Figure 1](#).

3.4

root diameter

diameter of the tap root

3.5

root number per 500 g

number of tap roots per 500 g

3.6

batch

samples collected from the same particular place at the same time

Note 1 to entry: This is not more than 5 000 kg.

3.7

final sample

samples after the final sampling

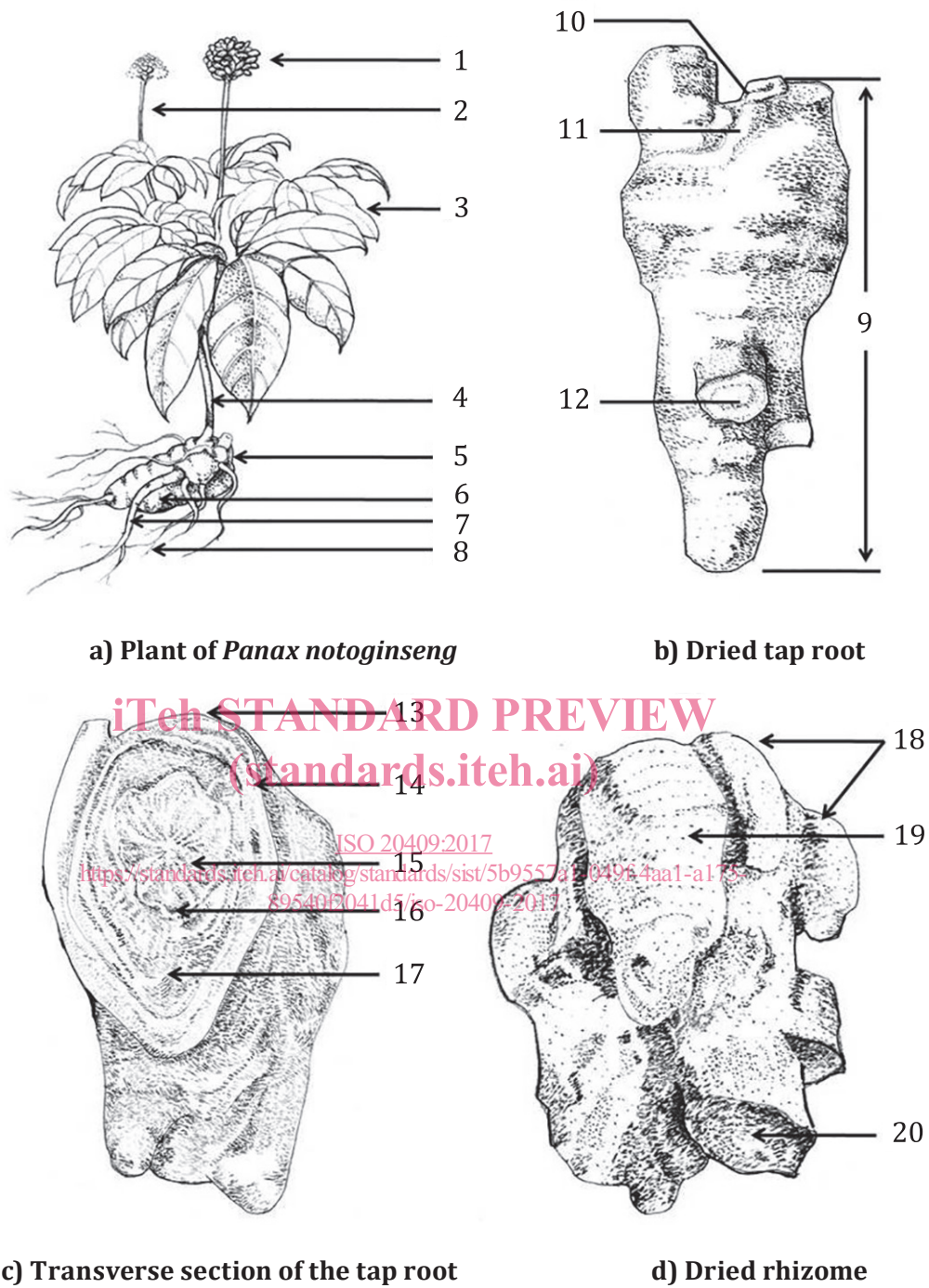
4 Descriptions

In this document, dried notoginseng root and rhizome consist of tap root, lateral root and rhizome, as shown in [Figure 1](#).

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Key

- | | | |
|----------------|----------------------|----------------------------|
| 1 fruit | 8 rootlets | 15 ray |
| 2 flower | 9 tap root length | 16 xylem |
| 3 leaf | 10 stem scar | 17 central cylinder |
| 4 stem | 11 warty protrusion | 18 stem scar |
| 5 rhizome | 12 lateral root scar | 19 strip-shaped protruding |
| 6 tap root | 13 epidermis | 20 root scar |
| 7 lateral root | 14 phloem | |

Figure 1 — Structure of notoginseng

5 Requirements

5.1 General characteristics

The following requirements shall be met before sampling.

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

5.2 Notoginseng root

5.2.1 Morphological features of root

- a) The shape of the tap root is subconical or cylindrical as shown in [Figure 1 b](#)).
- b) The root length is 1 cm to 6 cm long, and the root diameter is 1 cm to 4 cm.
- c) The outer surface is greyish-yellow or greyish-brown with intermittent longitudinal wrinkles and branch root scar.
- d) Stem scars at the apex are surrounded by warty protrusions.
- e) The texture is heavy and compact.
- f) The fracture is greyish-green, yellowish-green or greyish-white with xylem rays distributed radially.

5.2.2 Moisture

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The mass fraction of moisture shall not be more than 12,0% (w/w).

5.2.3 Total ash

The mass fraction of total ash shall not be more than 6,0 % (w/w).

5.2.4 Acid-insoluble ash

The mass fraction of acid-insoluble ash shall not be more than 1,0 % (w/w).

5.2.5 Ethanol-soluble extractives

The mass fraction of ethanol-soluble extractives shall be more than 16,0 % (w/w).

5.2.6 Identification of notoginsenoside R₁ and ginsenosides Rg₁, Re, and Rb₁

The identification of notoginsenoside R₁ and ginsenosides Rg₁, Re, and Rb₁ with thin-layer chromatogram (TLC) or high-performance liquid chromatogram (HPLC) shall present spots or peaks obtained from the test and reference solutions in the same position with the same colour (TLC) or same absorbance curve (HPLC).

5.2.7 Content of notoginsenoside R₁ and ginsenosides Rg₁ and Rb₁

The sum of the mass fraction of notoginsenoside R₁ and ginsenosides Rg₁ and Rb₁ shall be not less than 5,0 %. The content determination is carried out according to the method described in [Annex B](#).

5.2.8 Heavy metals

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

5.2.9 Pesticide residues

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

5.2.10 Root weight, root length and root number per 500 g

The root weight, root length and root number per 500 g of each batch of notoginseng root shall comply with the requirements in [Table 1](#). The quantity of roots that fail to meet the minimum weight requirement of the grade shall not be more than 5 %. Otherwise, it shall be considered to be of inferior grade.

Table 1 — Grading requirements of notoginseng root

Grade	Root weight g	Root length cm	Root number per 500 g
First	≥25,0	≤6,5	≤20
Second	≥17,0	≤6,0	≤30
Third	≥12,5	≤5,5	≤40
Fourth	≥8,5	≤4,5	≤60
Fifth	≥6,5	≤3,5	≤80
Sixth	≥4,5	≤3,0	≤120
Seventh	≥2,5	≤2,5	≤200
Unqualified	<2,5	>2,5	>200

NOTE 1 The root weight is determined when the moisture content of the tap root is approximately 12 %.

NOTE 2 The grading requirements are established according to the traditional grading system of notoginseng root and rhizome that has long been extensively used in the market and trading.

The grade shall be established only when all three requirements, i.e. root weight, root length, and root number per 500 g, are met.

5.3 Notoginseng rhizome

5.3.1 Morphological features of rhizome

The appearance of rhizome is irregularly shrunken, lump-shaped or slat-shaped, and there are several conspicuous stem scars and annulations on the surface of rhizome as shown in [Figure 1 d](#)). The fracture is greyish-green, or greyish-white in the centre and deep green or grey at margin.

5.3.2 Moisture

The mass fraction of moisture shall not be more than 14,0 % (w/w).

5.3.3 Total ash

The mass fraction of total ash shall not be more than 6,0 % (w/w).

5.3.4 Acid-insoluble ash

The mass fraction of acid-insoluble ash shall not be more than 3,0 % (w/w).

5.3.5 Ethanol-soluble extractives

The mass fraction of ethanol-soluble extractives shall be more than 20,0 % (w/w).