

Status: Currently Official on 17-Feb-2025
 Official Date: Official as of 01-May-2019
 Document Type: Dietary Supplement Monographs
 DocId: GUID-52742F29-AD20-420D-AA2E-2901AB23E716_4_en-US
 DOI: https://doi.org/10.31003/USPNF_M4985_04_01
 DOI Ref: a14rn

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Tienchi Ginseng Root and Rhizome

DEFINITION

Tienchi Ginseng Root and Rhizome consists of the dried roots and rhizomes of *Panax notoginseng* (Burkill) F.H. Chen ex C.Y. Wu & K.M. Feng (Fam. Araliaceae) collected before flowering in autumn. It contains NLT 5.0% of total ginsenosides calculated on the dried basis as the sum of notoginsenoside R1 ($C_{47}H_{80}O_{18}$), ginsenoside Rg1 ($C_{42}H_{72}O_{14}$), ginsenoside Re ($C_{48}H_{82}O_{18}$), ginsenoside Rb1 ($C_{54}H_{92}O_{23}$), and ginsenoside Rd ($C_{48}H_{82}O_{18}$).

IDENTIFICATION

Delete the following:

▲ **A.** It meets the requirements in *Specific Tests for Botanic Characteristics*. ▲ (USP 1-May-2019)

Change to read:

• ▲ **A.** [HPTLC FOR ARTICLES OF BOTANICAL ORIGIN \(203\)](#). ▲ (USP 1-May-2019)

Standard solution A: 0.5 mg/mL of [USP Ginsenoside Rg1 RS](#) in [methanol](#)

Standard solution B: 10 mg/mL of [USP Panax notoginseng Root and Rhizome Dry Extract RS](#) in [methanol](#). Sonicate for about 10 min, centrifuge, and use the supernatant.

Sample solution: Sonicate about 0.2 g of Tienchi Ginseng Root and Rhizome, finely powdered, in 5 mL of methanol for 20 min. Centrifuge, and use the supernatant. [NOTE—The *Sample solution* is stable for 6 h at room temperature.]

Chromatographic system

▲ (USP 1-May-2019)

Adsorbent: [Chromatographic silica gel F₂₅₄ mixture](#)

Application volume: 4 µL, as 8-mm bands

Relative humidity: Condition the plate to a relative humidity of about 33% using a suitable device.

Developing solvent system: [Methylene chloride](#), [dehydrated alcohol](#), and [water](#) ▲ (60:45:6.5) ▲ (USP 1-May-2019)

Developing distance: 6–8 cm

Derivatization reagent: A solution of 10% [sulfuric acid](#) in alcohol. Prepare fresh. Keep alcohol cold over ice. Carefully and gradually add [sulfuric acid](#).

Analysis

Samples: *Standard solution A*, *Standard solution B*, and *Sample solution*

Apply the *Samples* as bands to a suitable HPTLC plate, and dry in air. Develop the chromatograms in a saturated chamber, remove the plate from the chamber, and dry. Treat with *Derivatization reagent*, heat at 105° for 5–10 min, and examine immediately under white light and under UV light at 366 nm.

System suitability

Under white light: The chromatogram of *Standard solution B* exhibits five main reddish-violet bands in the following order with increasing R_F : a band in the lower-third section due to ginsenoside Rb1; three less intense bands clearly separated in the middle-third section—the lower due to ginsenoside Rd, the middle due to ginsenoside Re, and the upper due to notoginsenoside R1; and a band at an R_F corresponding to ginsenoside Rg1 in *Standard solution A*. The two most intense bands are due to ginsenoside Rb1 and ginsenoside Rg1.

Under UV light at 366 nm: The chromatogram of *Standard solution B* exhibits bands in the following order with increasing R_F : a blue fluorescent band in the lower-third section due to ginsenoside Rb1; three less intense bands clearly separated in the middle-third section—the lower due to ginsenoside Rd, the middle due to ginsenoside Re, and the upper due to notoginsenoside R1 (the band due to ginsenoside Rd is blue fluorescent, while the other two bands are pinkish violet); and a pinkish-violet band at an R_F corresponding to ginsenoside Rg1 in *Standard solution A*. The two most intense bands are due to ginsenoside Rb1 and ginsenoside Rg1.

Acceptance criteria

Under white light: The chromatogram of the *Sample solution* exhibits five main reddish-violet bands corresponding in R_f to similar bands in *Standard solution B*. These bands appear in the following order of increasing R_f : a band in the lower-third section due to ginsenoside Rb1; three less intense bands clearly separated in the middle-third section due to ginsenoside Rd, ginsenoside Re, and notoginsenoside R1, respectively; and a band at an R_f corresponding to ginsenoside Rg1 in *Standard solution A*. The two most intense bands are due to ginsenoside Rb1 and ginsenoside Rg1.

Under UV light at 366 nm: The chromatogram of the *Sample solution* exhibits the following bands, with increasing R_f , corresponding to similar bands in *Standard solution B*: a blue fluorescent band in the lower-third section due to ginsenoside Rb1; three less intense bands clearly separated in the middle-third section due to ginsenoside Rd, ginsenoside Re, and notoginsenoside R1, respectively (the band due to ginsenoside Rd is blue fluorescent, while the other two bands are pinkish violet); and a pinkish-violet band at an R_f corresponding to ginsenoside Rg1 in *Standard solution A*. The two most intense bands are due to ginsenoside Rb1 and ginsenoside Rg1.

Change to read:

• **▲B.▲** (USP 1-May-2019) **UHPLC**

Analysis: Proceed as directed in *Content of Ginsenosides*.

Acceptance criteria: The chromatogram of the *Sample solution* exhibits peaks at the retention times corresponding to notoginsenoside R1 (a distinction from *P. ginseng* and *P. quinquefolius*), ▲ (USP 1-May-2019) ginsenoside Rg1, ginsenoside Re, ginsenoside Rb1, and ginsenoside Rd in *Standard solution B*. The two most intense peaks are due to ginsenoside Rg1 and ginsenoside Rb1. The content of notoginsenoside R1 is NLT 0.6% as determined in *Composition*.

COMPOSITION

Change to read:

• **CONTENT OF GINSENOSES**

Solution A: 0.03% [phosphoric acid](#) in water (v/v)

Solution B: [Acetonitrile](#)

Mobile phase: See [Table 1](#).

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	83	17
2.4	80	20
3.5	70	30
4.2	69	31
5.0	58	42
5.1	0	100
6.0	0	100
6.1	83	17
7.5	83	17

Solvent: [Methanol](#) and [water](#) (7:3)

Standard solution A: 0.04 mg/mL of [USP Ginsenoside Rg1 RS](#) in ▲*Solvent*▲ (USP 1-May-2019)

Standard solution B: 3.0 mg/mL of [USP Panax notoginseng Root and Rhizome Dry Extract RS](#) in *Solvent*. Sonicate for about 10 min, centrifuge, and use the supernatant. Before injection, pass through a polytetrafluoroethylene (PTFE) filter of 0.2-μm pore size. ▲▲ (USP 1-May-2019)