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Tienchi Ginseng Root and Rhizome Dry Extract

DEFINITION

Tienchi Ginseng Root and Rhizome Dry Extract is prepared from 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, by extraction with hydroalcoholic mixtures. It contains NLT 90.0%–110.0% of the labeled amount of 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

• **A. HPTLC for Articles of Botanical Origin ⟨203⟩**

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 50 mg of Dry Extract, finely powdered, in 5 mL of methanol for 10 min. Centrifuge, and use the supernatant. [Note—The *Sample solution* is stable for 6 h at room temperature.]

Chromatographic system

Adsorbent: Chromatographic silica gel F_{254} 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)

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 band 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.

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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.

• **B. 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*), 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.

COMPOSITION

• **Content of Ginsenosides**

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*

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.

Sample solution: Transfer 75 mg of Dry Extract (capable of passing through a 250-µm sieve), accurately weighed, to a 50-mL centrifuge tube. Add 10 mL of *Solvent*, and sonicate for 10 min. Centrifuge, and transfer the supernatant to a 25-mL volumetric flask. Repeat this extraction two more times, each with 5 mL of *Solvent*. Combine the extracts in the volumetric flask, dilute with *Solvent* to volume, and mix. Before injection, pass through a PTFE filter of 0.2-µm pore size, and discard the first portion of the filtrate. [Note—The *Sample solution* is stable for 24 h at room temperature.]

Chromatographic system

(See *Chromatography ⟨621⟩, System Suitability*.)

Mode: UHPLC

Detector: UV 203 nm

Column: 2.1-mm × 5-cm; 1.7-µm packing L1

Column temperature: 30 ± 1°

Flow rate: 0.8 mL/min

Injection volume: 5 µL

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