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Tienchi Ginseng Root and Rhizome Dry Extract Tablets

DEFINITION

Tienchi Ginseng Root and Rhizome Dry Extract Tablets contain Tienchi Ginseng Root and Rhizome Dry Extract. They contain NLT 90.0% and NMT 110.0% of the labeled amount of ginsenosides calculated 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

Change to read:

• **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: 5 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: Transfer a portion of the powdered Tablets, equivalent to 50 mg of Tienchi Ginseng Root and Rhizome Dry Extract, to a conical flask, add 10 mL of [methanol](#), mix and sonicate for 20 min, centrifuge, and filter.

Chromatographic system

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 cm

Derivatization reagent: 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 visible light and under UV light at 366 nm.

System suitability

Under visible light: The chromatogram of *Standard solution B* exhibits five main reddish-violet bands. A band in the upper-half section corresponding in R_f to the band of ginsenoside Rg1 in *Standard solution A*; a band in the lower-third section due to ginsenoside Rb1; three less intense bands clearly separated between the bands of ginsenoside Rg1 and ginsenoside Rb1—the lower band due to ginsenoside Rd, the middle due to ginsenoside Re, and the upper due to notoginsenoside R1. 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 a pinkish-violet band at an R_f corresponding to the ginsenoside Rg1 band in *Standard solution A*; a blue fluorescent band in the lower-third section due to ginsenoside Rb1; three less intense bands clearly separated between the bands of ginsenoside Rg1 and ginsenoside Rb1—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). The two most intense bands are due to ginsenoside Rb1 and ginsenoside Rg1.

Acceptance criteria

Under visible light: The chromatogram of the *Sample solution* exhibits five main reddish-violet bands corresponding in R_f to similar bands in *Standard solution B*: a band in the upper-half section corresponding in R_f to the band of ginsenoside Rg1 in *Standard solution A*; a band in the lower-third section due to ginsenoside Rb1; three less intense bands clearly separated between the bands of ginsenoside Rg1 and ginsenoside Rb1—the lower band due to ginsenoside Rd, the middle one due to ginsenoside Re, and the upper due to notoginsenoside R1. 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 bands corresponding in R_f to similar bands in *Standard solution B*: a pinkish-violet band at an R_f corresponding to the ginsenoside Rg1 band in *Standard solution A*; a blue fluorescent band in the lower-third section due to ginsenoside Rb1; three less intense bands clearly separated between the bands of ginsenoside Rg1 and ginsenoside Rb1—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). The two most intense bands are due to ginsenoside Rb1 and ginsenoside Rg1.

• **B. LC**

Analysis: Proceed as directed in the test for *Content of Ginsenosides*.

Acceptance criteria: The retention times of the notoginsenoside R1, ginsenoside Rg1, ginsenoside Re, ginsenoside Rb1, and ginsenoside Rd peaks of the *Sample solution* correspond to those of *Standard solution B*. The two most intense peaks are due to ginsenoside Rg1 and ginsenoside Rb1.

STRENGTH

Change to read:

• **CONTENT OF GINSENOSES**

Extraction solvent: [Methanol](#) and [water](#) (70:30)

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

Standard solution A: 0.04 mg/mL of [USP Ginsenoside Rg1 RS](#) in ▲*Extraction solvent*.▲ (USP 1-May-2019) Sonicate to dissolve, if necessary.

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

Sample solution: Weigh NLT 20 Tablets, determine the average Tablet weight, and finely powder. Transfer a portion of finely powdered Tablets, nominally equivalent to 35 mg of ginsenosides (sum of notoginsenoside R1, ginsenoside Rg1, ginsenoside Re, ginsenoside Rb1, and ginsenoside Rd) into a 25-mL volumetric flask. Add 20 mL of *Extraction solvent*, and sonicate for 30 min with occasional shaking. Cool to room temperature, dilute with *Extraction solvent* to volume, mix well, centrifuge, pass the supernatant through a PTFE membrane filter of 0.2-μm pore size, and discard the first portion of the filtrate.

Chromatographic system

(See [Chromatography \(621\)](#), [System Suitability](#).)

Mode: LC

Detector: UV 203 nm

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